In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-738V

(to be published)

* *	Chief Special Master Corcoran
THEODORE MARTINEZ *and* SARAH MARTINEZ *as parents and natural guardians of W.M.*, *	
Petitioners, *	Dated: September 9, 2022
v. *	
SECRETARY OF HEALTH AND HUMAN SERVICES, *	
Respondent. *	
* *	

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioners.

Naseem Kourosh, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On June 22, 2016, Theodore and Sarah Martinez, on behalf of their minor daughter, W.M., filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioners allege that diphtheria-tetanus-acellular pertussis ("DTaP")[3]

[1] This Decision will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

[3] DTaP is the acronym for the version of the vaccine administered to infants and children younger than seven years of age, whereas "Tdap" is the version administered to adults. *Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=116510 (last visited Sept. 9, 2022).

and rotavirus vaccines administered to W.M. on June 26, 2013, caused their daughter to develop transverse myelitis ("TM"). A two-day entitlement hearing in the matter was held in Washington, D.C. on November 16-17, 2021.

Having reviewed the record, all expert reports and associated literature, and listened to the testimony at hearing, I hereby deny an entitlement award. As discussed in greater detail below, Petitioners have not preponderantly established that W.M.'s TM occurred within a medically acceptable timeframe.

I. Fact History

Early Life and Vaccination Event in Question

W.M. was born on December 23, 2012, to Petitioners. Ex. 7 at 31–37, 64; Ex. 10 at 24. She was born prematurely at 34 weeks as an identical twin. *Id.*

On December 27, 2012, W.M. received a Hepatitis B vaccine for her first-week wellness check. Ex. 2 at 4. On March 6, 2013, W.M. was seen by her pediatrician at the Affinity Clinic for a two-month check-up. Ex. 8 at 28, 31–32. During this visit she received Pediarix (a combination of DTaP, Hepatitis B, and Polio vaccines), ActHIB (haemophilus influenza type B ("Hib")), Prevnar 13 ("pneumococcal"), and the RotaTeq ("rotavirus") vaccines. *Id.* Her exam during this visit was normal. *Id.* She had a four-month well-child check-up at Affinity Clinic on April 23, 2013, at which time she received the DTaP, Hepatitis B, Polio, Hib, pneumococcal, and rotavirus vaccines. Ex. 8 at 33–37. A six-month visit followed on June 26, 2013. Ex. 8 at 38, 42. Her exam was again normal, and she received the DTaP and rotavirus vaccines at issue that afternoon (at 2:46 and 2:48 P.M, respectively). *Id.*

Onset of Symptoms

W.M. returned to the Affinity Clinic approximately five days later, on July 1, 2013. Petitioners now reported that after receiving her DTaP vaccine the prior week, W.M. had not been moving or bearing any weight on her legs, and had a tremor when trying to stand or use her arms. Ex. 8 at 43. They also informed treaters that she was constipated, hypotonic (meaning low muscle tone), lethargic, not acting like herself, and had a fever of 100.9 degrees, and that her symptoms were not worsening but also not improving either. *Id.* Mrs. Martinez specifically expressed a concern about the possibility of seizures. *Id.*

No specific onset date for this constellation of symptoms was provided at this time, however, beyond the general assertion that they had manifested "since" the time of vaccination. And there is no record filed in this case of any intervening doctor's visit prior to the encounter at Affinity Clinic on July 1. At most, Mrs. Martinez has averred (in a June 23, 2016 affidavit) that

after receiving the DTaP and the rotavirus vaccines, both W.M. and her twin sister[4] were tired, a bit cranky and had sore legs from the injections. Ex. 18 at 2. However, after a few days, Mrs. Martinez became concerned for W.M. specifically because she continued to be lethargic, and was not moving her legs while her twin sister had recovered from any initial apparent vaccine reaction. Ex. 9 at 2; Ex. 18 at 2. Furthermore, Mrs. Martinez has alleged that Mr. Martinez took W.M. to the Affinity Clinic urgent care on June 29, 2013 (a Saturday), but that there is no record of this visit because he only briefly spoke with a doctor in the waiting room. Ex. 8 at 43 (noting that this may be the interaction referred to in the July 1, 2013 record, which stated (under Chief Complaint) "[s]een by Dr. [Teresa] Stewart in EC on 6/29/13"); Ex. 18 at 3.

At the Affinity Clinic visit on July 1, 2013, W.M. was seen by nurse practitioner Ramona Cawley. Ex. 8 at 43. Petitioners (who were deemed in the record to be "very familiar" with the relevant history) reported that W.M. would not move her legs or bear weight on them "since" the vaccination event (although no specific onset was identified). *Id.* The record also noted that she had been constipated. *Id.* Overall, her symptoms were deemed to be "not worsening but also not improving over time." *Id.* Exam showed that W.M. would not bear weight on her legs, had limited active movement in her lower extremities, and a tremor in her arms when reaching. *Id.* at 44. The assessment was generalized muscle weakness, and W.M. was referred to neurology. *Id.*

Two days later (July 3, 2013), W.M. was seen by pediatric neurologist Yong Park, M.D. Ex. 9 at 7. Petitioners informed Dr. Park that W.M. had been doing well until she received the DTaP vaccine the week prior, after which she was very cranky and stopped using her legs. *Id.* They also reported that W.M.'s twin sister had received her vaccinations without any problems, and there was no family history of neurological disorders. *Id.* It was also noted that the neurologic referral occurred because W.M.'s symptoms had "progressed"—and since the referral occurred on July 1 (two days before Dr. Park saw W.M.), this reasonably means that the progression occurred *up to* July 1 rather than after.

Upon physical exam, Dr. Park noted that W.M.'s lower extremities showed spasticity and clonus, which were more pronounced on the left than right side. Ex. 9 at 7. There was also hyporeflexia and brisk deep tendon reflexes ("DTRs") in the lower extremity, minimal reaction to stimulation on the left leg. and a wink in the anal sphincter tone. *Id.* at 7–8. Dr. Park's assessment was spastic paraparesis "acute in onset since 2nd [DTaP] vaccination." *Id.* at 8. He noted that he was concerned about a vaccination reaction such as TM, but that a spinal cord lesion was in his opinion unlikely due to W.M.'s clinical presentation. *Id.* Dr. Park made an urgent transfer to the hospital for W.M. to undergo further testing, which was to include a spinal tap/lumbar puncture ("LP") and MRI. *Id.*

[4] Although it was not evidenced by the medical records at this time, W.M.'s twin sister, R.M., also received the DTaP and rotavirus vaccines on June 26, 2013. Ex. 18 at 2; Tr. at 135, 187–88.

Hospital Admittance

That same day, W.M. was admitted to the Children's Hospital of Georgia. Ex. 10 at 21. Upon admission, Mrs. Martinez provided additional specific information about the circumstances of W.M.'s symptoms manifestation—and again suggested an onset close in time to the vaccination date. W.M., she reported, had received the DTaP and rotavirus vaccines on June 26, 2013, and after returning home developed a decreased activity level (including less rolling) that evening, and had a temperature of 99 degrees. *Id.* at 24. By the next morning (June 27, 2013), both of W.M.'s legs were limp, and she continued not to move her lower extremities or stand on her legs. *Id.* In addition, W.M. now had a temperature of 100.9 degrees, which continued through that day. *Id.* And as of June 28, 2013, both of W.M.'s legs were stiff, and at some point around this time, her stools became more frequent and of lesser quantity, although her urination pattern was normal. *Id.* at 3, 24.

W.M. was also examined by George Lazari, M.D., PGY1,[5] and an attending physician. He reported that the chief complaint was that W.M. was "limp after shots." Ex. 10 at 24. He also completed a musculoskeletal exam, which revealed "[d]ecreased range of motion, [s]pasticity and decreased movements in lower extremities." *Id.* at 25. Treating physicians had a differential diagnosis of Guillain-Barré syndrome ("GBS") or transverse myelitis. *Id.* at 27. An MRI done that same day showed thoracic spinal cord intermedullary enhancement at T3-T4 that was concerning for early stages of acute TM. *Id.* at 97–98. The LP performed that day showed slightly elevated protein of 51 and slightly decreased glucose of 38, RBC 1, WBC 3 with 59 percent lymphocytes and 41 percent monocytes. *Id.* at 53–54, 92. CSF Oligoclonal bands were negative, however, and CSF myelin basic protein was elevated at 6.40 ng/mL. *Id.* at 93–94.

W.M. was then evaluated by pediatric neurologist Suzanne Strickland, M.D. on that same day (July 3, 2013). Ex. 10 at 57. Dr. Strickland considered W.M.'s prior history reported by her mother, as well as the written pediatric transfer note and additional medical documentation. *Id.* at 57, 62–66. Based on these disclosures plus the testing results, Dr. Strickland diagnosed W.M. with TM, deeming W.M.'s radiology results and clinical presentation as consistent with this diagnosis. *Id.* at 54, 61.

W.M. was subsequently administered a high dose of methylprednisolone over the next five days. Ex. 10 at 4–6. Her lower extremity movement began to improve on the second day, and her neurological exam improved slightly each day, but she was still moving significantly less than normal. *Id.* She was discharged on July 7, 2013, with a diagnosis of TM and instructions to continue oral steroids. *Id.* at 5–6.

[5] This indicates that it was the first year of graduate training after completion of medical school.

Post-TM Diagnosis Treatment

On July 12, 2013, W.M. presented for outpatient physical therapy ("PT"), with her parents. Petitioners now reported that within hours of receiving a DTaP vaccine, W.M. developed extreme weakness, tremulousness, and lethargy. *Id.* at 1. A few days later, on July 15, 2013, W.M. was seen in a follow-up appointment at the Affinity Clinic, with Mrs. Martinez informing treaters that W.M. was doing better with leg movements, and that she was receiving oral steroids in conjunction with her PT sessions. *Id.* at 50.

On August 1, 2013, W.M. returned to the Affinity Clinic and was seen by pediatrician Dixie Griffin, M.D. Ex. 8 at 54. W.M. was now reported to be doing well—moving her lower extremities, trying to crawl, urinating—but had mild constipation, and was shaking her head. *Id.* Dr. Griffin noted that she discussed vaccines with Mrs. Martinez, noting the close temporal relationship of the onset of W.M.'s symptoms following vaccination but nevertheless stating that "I do not feel [acute transverse myelitis] is related to DTaP vaccinations because symptoms occurred 2 days after vaccine(s). Most studies suggest 2–3-week lag between inciting event and A[cute] TM." *Id.* at 54–55.

On August 5, 2013, W.M. was seen by neurologist Sheisa Claudio-Sandoval, M.D. Once again, Petitioners stated that W.M. had manifested symptoms associated with TM within a few hours of receiving a DTaP vaccine. Ex. 10 at 448. Dr. Claudio-Sandoval concurred in the TM diagnosis. *Id.* at 450. A month later, on September 4, 2013, W.M. was seen at the Affinity Clinic by NP Cawley. Ex. 8 at 72. NP Cawley noted that Mrs. Martinez was concerned about vaccines and reported that neurology had told her to wait on further vaccination. *Id.* at 73. NP Cawley discussed this issue with Dr. Griffin, who suggested that W.M. be referred to an infectious disease specialist so that she could discuss her vaccine concerns. *Id.*

W.M. next went to an outpatient clinic and saw neurologist James Carroll, M.D., on September 17, 2013. Ex. 10 at 469. W.M. was reported to have demonstrated improvement since her PT, and an exam confirmed that many symptoms and associated issues had diminished. *Id.* at 469–70. An MRI performed that day showed that the spinal cord lesion at T3-T4 was resolved and no new lesions were identified. *Id.* at 473. The improvements were also reflected in the record from W.M.'s nine-month check-up at the Affinity Clinic on September 25, 2013. Ex. 8 at 80, 82.

Treatment in 2014 and Thereafter

Months later, on June 5, 2014, W.M. began services with an early intervention program focusing on PT to improve motor skills. Ex. 12 at 2. Neurology outpatient visits confirmed her progress—although many deficits remained. Ex. 10 at 505–06. This incomplete improvement

remained a constant for the remainder of the year. *See, e.g.*, Ex. 7 at 154 (July 9, 2014 Affinity Clinic check-up); Ex. 13 at 1, 3 (December 4, 2014 primary care visit).

W.M.'s course since the start of 2015 is consistent, demonstrating improvement without elimination of prior issues—and no recurrence of new neurologic concerns that might suggest her TM did not reflect a single monophasic event. One pediatric neurologist—William Taft, M.D.—who saw W.M. in January 2015 did propose that a real link between her vaccination to neurologic symptoms was evident, and asked to see other testing results to explore the possibility further. Ex. 14 at 1–2. Mrs. Martinez has stated that W.M. continues to have pain and displays "difficulty walking long periods of time or long distances; difficulty running; [gait] issues and concerns; balance issues and concerns; short tendons and tight muscles; hip joint concerns; some bladder and constipation concerns and frequently asks to wear a pull up; issues dressing and undressing; and poor balance and flexibility." Ex. 9 at 4. W.M. uses a walker for distances, AFOs, and orthotic shoes. *Id.*

II. Witness Testimony

A. Petitioner's Fact Witnesses

1. *Ms. Sarah Martinez* – Mrs. Martinez, W.M.'s mother, was the first witness to testify at the hearing. *See generally* Tr. 7–90. She began with an overview of the first sixth months of W.M.'s life. *Id.* at 9–13. As she recalled, W.M. (and her twin sister R.M.) were developing normally and hitting their milestones prior to their sixth-month wellness check. *Id.* at 10, 12, 48. The twins attended other wellness checks after their birth, where they received vaccines. *Id.* at 9. Thus, at the first-week wellness check they both received the Hepatitis B vaccine, at the two-month wellness check they received the pneumococcal, rotavirus, Hib, and Pediarix vaccines, and at the fourth-month wellness check they received the second dose in the series for the pneumococcal, rotavirus, Hib, and Pediarix vaccines. *Id.* at 9, 11–12. Mrs. Martinez noted that after the two-month and four-month wellness check vaccinations, the twins appeared fatigued, but returned to their normal behaviors the following day. *Id.* at 12.

During their six-month wellness check, on June 26, 2013, the twins received the DTaP and rotavirus vaccines. *Id.* at 13–14. Prior to the administration of these vaccines, Mrs. Martinez recalled, neither twin had recently suffered from any kind of infection or illness. *Id.* at 12. However, after the girls returned home and Mrs. Martinez went out to dinner with her husband that night, she was told by her mother (who was watching the girls) to come back because the twins were upset. *Id.* at 15, 51–52, 62; Ex. 18 at 2.

When Mrs. Martinez returned, she found the girls irritable, crying, and lethargic, with elevated temperatures around 99 degrees. Tr. at 15–16, 53–54, 62. Mrs. Martinez gave them each a dose of Tylenol before bed, but the next morning (June 27, 2016), the girls were exhibiting

similar symptoms of irritability, lethargy, and elevated temperatures around 100.7 degrees. *Id.* at 17. Mrs. Martinez also noticed that on all other nights the twins would move around, and she would find them in different positions the following morning, but on this night, she found them in the exact same positions she placed them in the night before. *Id.* at 55–57. Although their temperatures dissipated after another dose of Tylenol, the other symptoms continued, and the twins would not engage in their normal activities of moving around and playing. *Id.*

The following day (June 28, 2013), however, the twins started to display different symptoms, with R.M. improving while W.M.'s symptoms remained consistent with the day before. Tr. at 19, 59. Mrs. Martinez observed that W.M. did not want to move her upper or lower body when laying down and required a lot of holding and breastfeeding for comfort. *Id.* at 70. Mrs. Martinez maintains she did not at this time notice anything abnormal in W.M.'s legs (even though statements from the contemporaneous medical record do contain these kinds of observations), though she admits she did nothing to informally examine W.M. in this regard at this time. *Id.* at 70, 85. She called the pediatrician's nurse hotline and was told that this behavior was normal after receiving a vaccination due to injection site soreness, and was not recommended to go to the hospital. *Id.* at 20–21.

On June 29, 2013, R.M. improved significantly and was almost back to her usual self, but not W.M. Tr. at 22–23, 62. As a result, Mr. Martinez took W.M. to the Affinity Clinic urgent care center, where they were reassured that W.M. was simply irritable from the injection site. *Id.* at 23–24, 62–63. They were advised to take her to a pediatrician on Monday (July 1) if her symptoms did not improve. *Id.* at 24, 63. On June 30, Mrs. Martinez noted slight improvement such as alertness and more active movement with her hands, but W.M. had now also developed severe constipation that caused bleeding (although the bleeding was not mentioned in the medical record). *Id.* at 25–26, 28, 60, 64–66. Up until this point, W.M. was urinating and passing stools normally. *Id.* at 17, 20, 22.

On July 1, 2013, Mrs. Martinez called the Affinity Clinic, as W.M. still appeared lethargic. She was told that W.M.'s symptoms were normal but was given a same-day appointment with NP Cawley, who had conducted the twins' well-check visits previously. Tr. at 28–30, 64, 87. Mrs. Martinez testified that NP Cawley had consulted with another pediatrician, Dr. Griffin, at this time. *Id.* at 31–32. Dr. Griffin said that he wanted W.M. evaluated by a pediatric neurologist, but Mrs. Martinez was not told that it was an urgent issue. *Id.* at 32–33.

Upon leaving the Affinity Clinic, Mrs. Martinez testified that she noticed for the first time that W.M. had begun straightening out her legs rigidly and then bending her knees, before relaxing and then repeating this behavior. *Id.* at 35–36, 61–62, 83–84. Mrs. Martinez denied specific concerns with W.M.'s legs before this time, but it was not until after NP Cawley had completed her physical examination. Tr. at 66, 80; Ex. 9 at 7.

W.M. was subsequently evaluated at an outpatient neurological visit by Dr. Park on July 3, 2013, and at that point Mrs. Martinez described what she had witnessed of W.M.'s behavior after the last Affinity Clinic visit. *Id.* at 34–35. (She again took issue with contemporaneous medical record evidence from the time of this visit suggesting that the Petitioners had previously observed W.M.'s leg issues closer-in-time to vaccination). Tr. at 66, 85; Ex. 10 at 24, 55. Dr. Park stated that this behavior indicated neurological issues and wanted to confirm with testing as it suggested acute TM. *Id.* at 36–37, 84.

There was, Mrs. Martinez recalled, now a new sense of urgency as Dr. Park sent the family immediately to the Medical College of Georgia, where the family was met with a handful of doctors conducting diagnostic tests. Tr. at 38–40. Mrs. Martinez described several instances where she gave a rushed explanation to multiple doctors of W.M.'s medical history, with short follow-up questions (since the treaters were focused on W.M.'s care). *Id.* at 40–42, 71. During this time she noticed that W.M.'s upper body movements had returned to her usual state. *Id.* at 45. After a spinal tap and MRI, the doctors diagnosed W.M. with TM. *Id.* at 44.

W.M. was subsequently admitted to the hospital in early July and discharged on July 7, 2013. Tr. at 45. During that time Mrs. Martinez had conversations with doctors regarding the cause of W.M.'s injuries. *Id.* Specifically, Dr. Strickland and Dr. Carroll discussed the role vaccinations could have played on W.M.'s injury, as there were no prior events of note, although treaters hesitated to predict future treatment requirements or likely outcomes. *Id.* at 46, 47. As of the date of the hearing, W.M. was eight years old, and used assistive devices like ankle foot orthotics and forearm crutches to get around. *Id.* at 47.

Besides the foregoing, Mrs. Martinez also attempted to correct medical records that she deemed inaccurate or incomplete. Tr. at 77–80. For example, she identified W.M.'s appointment with Dr. Claudio-Sandoval on August 5, 2013, where the history stated that "[W.M.] was admitted to PICU on July 3, 2013, *after develop[ing] low extremity weakness after a few hours of receiving second DTaP dose*." Tr. at 78; Ex. 10 at 448 (emphasis added). Mrs. Martinez contended, to the contrary, that W.M. was simply lethargic after receiving this vaccine. Tr. at 79. Additionally, she questioned the accuracy of the record of W.M.'s appointment with Dr. Taft on January 30, 2015, which reported under history of present illness that "[p]arents report that [W.M.] was doing well *until the day after she received her DTaP. That night she began to exhibit flaccid weakness* of her legs on both sides. Her arms were moving appropriately, and she was cognitively normal." *Id.*; Ex. 14 at 1 (emphasis added). Mrs. Martinez maintained that she had not noticed anything abnormal in terms of W.M. bearing weight on her legs immediately after vaccination, and that she had simply appeared lethargic. Tr. at 79–80.

2. *Mr. Theodore Martinez* – Mr. Martinez (W.M.'s father) was the second witness to testify at the hearing, and his testimony was generally consistent with Mrs. Martinez's testimony. *See generally* Tr. at 91–118. He characterized W.M. and R.M.'s development as normal

prior to vaccination, and noted they were beginning to make noises, crawl, and roll. *Id*. at 93, 106. He did not see signs of illness in either twin in the days leading up to their vaccination. *Id*. at 104. But two days later, W.M. and R.M. were extremely lethargic, crying more, and their voices were weaker than usual. *Id*. at 94–95, 106. He noticed that they did not want to play as they typically did, but only wanted to be held and fed. *Id*. at 106.

On June 28, 2013, R.M. improved and became more active, but W.M. remained lethargic. Tr. at 95–96, 106. That day, Petitioners called the nurse hotline, but wanted to see a doctor in person, so Mr. Martinez took W.M. to urgent care the next day due to her ongoing lethargy, where he saw Dr. Stewart. *Id*. at 96–97. (There remains a factual dispute about this visit that was never resolved, despite the parties' efforts and although this visit was discussed in Mrs. Martinez's affidavit, there is no formal record of it). Tr. at 96–97; Ex. 18 at 3.[6] W.M. never went into an examination room but remained in her car seat in the lobby, where Dr. Stewart checked W.M.'s reflexes, deeming them normal (beyond inflammation at the vaccination site). Tr. at 98, 100, 106, 108-09, 118. She advised Mr. Martinez to continue giving W.M. Tylenol as needed, adding that W.M. should be taken to Dr. Griffin on Monday if her symptoms persisted. *Id*. at 98–99, 109–110.

W.M. subsequently saw Dr. Park on July 3, 2013. Tr. at 102, 110. During this visit, Mr. Martinez recalled that Dr. Park became concerned with W.M.'s leg movements and subsequently rushed the family to the hospital for treatment. *Id*. at 102–03, 110, 117. There, Mrs. Martinez was mostly responsible for providing specifics about W.M.'s more-recent medical history. *Id*. at 103–1\04. Mr. Martinez also recalled that during W.M.'s hospitalization, Dr. Taft and other treaters had discussed W.M.'s TM and its possible links to her vaccinations. *Id*. at 104.

B. Petitioner's Experts

1. *Justin Willer, M.D.* – Dr. Willer, a board-certified neurologist with a subspeciality in neuromuscular diseases and epilepsy, submitted four written expert reports and testified for Petitioners. *See generally* Tr. at 120–227. Report, dated Jan. 12, 2018, filed as Ex. 20 (ECF No. 31-1) ("Willer First Rep."); Report, dated Mar. 15, 2019, filed as Ex. 28 (ECF No. 41-1) ("Willer Second Rep."); Report, dated Nov. 8, 2019, filed as Ex. 31 (ECF No. 52-1) ("Willer Third Rep."); Report, dated Mar. 13, 2020, filed as Ex. 34 (ECF No. 59-1) ("Willer Fourth Rep."). Dr. Willer did not, however, offer any opinion specific to the "can cause" causation issues in dispute, leaving that topic to Petitioners' other expert.[7]

[6] Petitioners subpoenaed the Affinity Clinic, but despite their best efforts were not able to obtain a record of this specific visit. ECF Nos. 88-89.

[7] One of Respondent's expert, Dr. Lotze, criticized some of Dr. Willer's publications addressing autoinflammatory syndrome induced by adjuvants ("ASIA") syndrome, but Dr. Willer did not allege in this case that aluminum contained in the vaccine was the cause of W.M.'s TM. Willer Third Rep. at 4; Lotze Second Rep. at 2; R. Ameratunga et al., *Evidence Refuting the Existence of Autoimmune/Autoinflammatory Syndrome Induced by Adjuvants (ASIA)*, 5 J.

Dr. Willer received his undergraduate degree from Columbia College of Columbia University and his medical degree from the University of Health Sciences/The Chicago Medical School. *See* Curriculum Vitae, filed Oct. 27, 2021 (ECF No. 84-1) ("Willer CV") at 1; Tr. at 121. Beginning in 1995, he has held hospital appointments at University Hospital, Long Island College Hospital, Maimonides Hospital Medical Center, and Kings County Medical Center, but he has not treated pediatric patients since 2000. Willer CV at 1; Tr. 122–23, 176. He has also held academic appointments as a Neuromuscular Consultant and Assistant Professor of Clinical Neurology at the State University of New York, HSC at Brooklyn. Willer CV at 1; Tr. at 123. He is licensed to practice medicine in New York, New Jersey, and Florida, and is board certified by the American Board of Psychiatry and Neurology, with added qualifications in clinical neurophysiology, and American Board of Electrodiagnostic Medicine. Willer CV at 2; Tr. at 122–23. None of Dr. Willer's publications are related to pediatric neurology, TM, or other autoimmune diseases. Tr. at 176.

Dr. Willer began his testimony with an overview of W.M.'s diagnosis. He opined that she had experienced TM,[8] with her initial symptoms rapidly progressing to hypertonicity and then spastic paraparesis. Tr. at 126–27. In so proposing, he defined some of the terms he was using applicable to W.M.'s muscle and motor-related symptoms. *Id.* Human limbs generally display some amount of muscle resistance as they are moving, but where the resistance is more labile, "hypotonicity" is displayed, as opposed to "hypertonicity," which occurs in the presence of muscle rigidity. *Id.* at 133–34. The outset of TM is typically characterized by hypotonia, which subsequently progresses to hypertonia unless there is "deafferentation" (meaning where the sensory supply to the lower limbs becomes completely cut off). *Id.* at 133. Dr. Willer also defined spastic paraparesis as weakness of two arms or two legs (as relevant to W.M.) with increased tone. *Id.* at 134. In TM, there is an initial phase where tone is decreased (consistent with hypotonia) before it increases. *Id.* at 179.

As Dr. Willer explained, TM is a rapidly evolving disease, reaching nadir between 4-21 days from its start and involving spinal cord demyelination. Tr. at 129, 132–33, 178; Willer First

Allergy Clinical Immunology 1551, 1551–54 (2017), filed as Ex. C-1 (ECF No. 49-2). At most, Dr. Willer argued that vaccines produce antibodies that cause TM, which are similar or identical to the antibodies causing TM by natural infection, but deferred to Dr. Gershwin on such matters more generally. Willer Third Rep. at 4.

[8] Dr. Willer's written reports had also discussed a possible diagnosis of acute disseminated encephalomyelitis ("ADEM"), which he felt could not be ruled out given the absence of MRI imaging results that would bear on such a diagnosis. Tr. at 179; Willer First Rep. at 9; Willer Second Rep. at 4–5; Willer Third Rep. at 5. He contended there was at least case report support for the proposition that tetanus-containing vaccines can cause ADEM. *See, e.g.*, F. Cisse et al., [*Acute Disseminated Encephalomyelitis After Tetanus Vaccination of a Pregnant Woman in Senegal*], 22 Médecine et Santé Tropicales 103, 103–05 (2012), filed as Ex. 26 (ECF No. 32-6). But at trial he made it clear that he accepted and favored TM as the proper diagnosis. Tr. at 179.

Rep. at 4. Although often idiopathic, (meaning no cause can be identified),[9] it can be attributable to infectious/post-infectious causes (or vaccination). Tr. at 129, 170; Willer First Rep. at 4. It can also be the presenting symptom of a larger disease, like multiple sclerosis ("MS") or neuromyelitis optica spectrum disorder ("NMOSD"). Tr. at 170–71, 222. TM can feature sensory symptoms, weakness, bowel or bladder complaints, urinary retention, constipation, or pain. *Id.* at 129. The typical work-up to identify its cause begins first with eliminating an injury from outside the spinal cord through imaging studies, followed by an LP aimed at identifying signs of inflammation or other biomarkers associated with known causal diseases (for example, oligoclonal bands, which are associated with MS), and then an antibody test. *Id.* at 130. An MRI can assist in diagnosis as well, since it can reveal a breakdown of the blood-brain barrier and the presence of active lesions or inflammation. *Id.* at 130. After diagnosis, treatment consists of steroids during initial symptoms, although treatment approaches require adjustment depending on its ultimate determined etiology. *Id.* at 131; Willer First Rep. at 5.

Next, Dr. Willer addressed the medical record, attempting to demonstrate how it supported the conclusion that the DTaP vaccine could have caused W.M.'s TM.[10] Tr. at 166, 179–80; Willer Third Rep. at 6; Willer Fourth Rep. at 3. There was no evidence that W.M. had any type of viral or bacterial illness prior to vaccination or during her pediatric visits and hospital visit. Tr. at 135, 170–72, 226–27. W.M. was never diagnosed with MS or NMOSD. *Id.* at 170–72, 215. And even though Dr. Willer found some of Dr. Park's information lacking from the July 3, 2013 progress notes, Dr. Park seemed to embrace the possibility that W.M.'s vaccination had caused her TM. *Id.* at 158–59; Ex. 9 at 8. Because Dr. Park is a pediatric neurologist likely familiar with neurologic complications of vaccines in children, his views deserved extra weight in Dr. Willer's opinion. Tr. at 159–60.

In addition, other treaters at the hospital also questioned whether W.M.'s injury was caused by vaccination (although some speculated about a possible infectious cause). Tr. at 172–75, 205–07; Ex. 10 at 65 (noting an impression that W.M.'s injury was vaccine induced), 68 (contemplating a vaccine reaction versus an infectious/post-infectious case), and 70 (indicating a potential vaccine or viral illness caused W.M.'s injury); Ex. 14 at 2 (stating that W.M.'s injury occurred after vaccination, but too vague to indicate whether the treater thought it was caused by vaccination). No other physician—either Dr. Park or a treater at the hospital—suggested an idiopathic etiology, and Dr. Willer felt that the likelihood of idiopathic TM in a six-month-old was low in any event. Tr. at 171.

[9] Though in a few medical records the treaters contemplate whether the injury was caused by vaccination or a viral illness, and thus seem unable to identify a cause, Dr. Willer was careful to iterate that this was not the same as an *affirmative* determination that idiopathic best described TM's cause in this case. *Id.* at 207–08.

[10] Dr. Willer briefly discussed W.M.'s receipt of the rotavirus vaccine (also received on June 26 along with the DTaP vaccine) but deemed it less likely causal. Tr. at 180; Willer Second Rep. at 3. Literature Petitioners otherwise relied upon did not show a TM-rotavirus vaccine association. Willer Second Rep. at 3 (citations omitted).

Dr. Willer deemed the temporal relationship between W.M.'s onset and date of vaccination consistent with causation by the DTaP vaccine. Tr. at 216; Willer First Rep. at 9; Willer Second Rep. at 3; Willer Third Rep. at 6. He proposed that TM could begin after a vaccine trigger any time between three to four days to a few weeks post-vaccination, although onset within two days was also possible. Tr. at 167. In support, Dr. Willer referenced several case reports. *Id.* at 167–69, 185–87; Willer First Rep. at 4; Willer Fourth Rep. at 1, 5; N. Agmon-Levin et al., *Transverse Myelitis and Vaccines: A Multi-Analysis*, 18 Lupus 1198, 1200 (2009), filed as Ex. 25 (ECF No. 32-5) ("Agmon-Levin") (finding the shortest onset for TM occurred two days after a rabies injection, and another case of TM with an onset of 4 days following rubella vaccination—but most other cases occurred after a few weeks); R. Riel-Romero, *Acute Transverse Myelitis in a 7-Month-old Boy After Diphtheria-Tetanus-Pertussis Immunization*, 44 Spinal Cord 688, 688–91 (2006), filed as Ex. 22 (ECF No. 32-2) (noting that an individual with an upper respiratory infection two weeks prior to onset developed TM 17 days post-vaccination) ("Riel-Romero"); E. Whittle & N. Robertson, *Transverse Myelitis After Diphtheria, Tetanus and Polio Immunisation*, Brit. Med. J. 1450, 1450 (1977), filed as Ex. 23 (ECF No. 32-3) (finding onset began 6-17 days post-vaccination) ("Whittle"); D. Karussis & P. Petrou, *The Spectrum of Post-Vaccination Inflammatory CNS Demyelinating Syndromes*, 13 Autoimmunity Revs. 215, 221 (2014), filed as Ex. 24 (ECF No. 32-4) (stating that the authors inferred vaccine causation of TM based on case reports of temporal association).

Dr. Willer then turned to W.M.'s own medical history, arguing that the record supported the conclusion that her symptoms most likely began on June 30, 2013—four days post-vaccination. Tr. at 166, 175, 189, 217; Willer Second Rep. at 3; Willer Fourth Rep. at 1–2. Although this was not discussed in detail his expert reports,[11] he relied on trial testimony about W.M.'s symptoms (in particular, her constipation) for his determination. Tr. at 128, 164–65, 189–90. The Petitioners' testimony had persuaded Dr. Willer that W.M.'s bleeding from severe constipation (which purportedly began on June 30) suggested the presence of intra-abdominal pressure,[12] which typically causes hemorrhoids to bleed. *Id.* at 128, 137, 139. This kind of constipation would be an outward manifestation of the neurologic harm attributable to TM.[13] *Id.*

Other parts of the medical record, Dr. Willer maintained, corroborated his proposed onset date. Tr. at 140–66. He started with the July 1, 2013 pediatric visit, chronologically the next

[11] Dr. Willer specifically explained that the description of constipation in the medical records did not invoke the gravitas that Ms. Martinez explained in her testimony, which changed Dr. Willer's assessment of the clinical picture significantly. Tr. at 190–91, 218–19.

[12] It could not, Dr. Willer believed, have been evidence of bleeding coming from the GI tract because this would cause rapid bowel movements as opposed to constipation. Tr. at 128, 137, 139.

[13] Dr. Willer did not address this issue in depth in his expert reports as the severity of W.M.'s constipation was not revealed to him until the hearing. Tr. 127–28.

medical record after the June 26 vaccination. Tr. at 141; Ex. 8 at 43. Under history of present illness, it notes that Mrs. Martinez was "complaining of [W.M.] being lethargic and hypotonic. . . [w]ill not move legs and does not bear [weight] on legs since getting DTaP." Tr. at 143; Ex. 8 at 43. The physical exam did not discuss an assessment of stiff legs, clonus, hypertonicity, or spastic paraparesis—all of which Dr. Willer would expect to have manifested had onset begun closer in time to vaccination. *Id.* at 146–49; Ex. 8 at 44.[14] Then there were the notes from the July 3 visit with Dr. Park. Tr. at 152–55; Ex. 9 at 7; Willer Fourth Rep. at 2. Unlike the July 1 encounter, the exam from this later visit clearly noted that W.M. had displayed spasticity, and otherwise evidenced disease progression since the earlier treater event—bulwarking the conclusion that W.M.'s course was moving toward nadir since that time. Tr. at 156–57; Willer Third Rep. at 3.

Dr. Willer rejected the possibility that W.M.'s TM onset occurred within or just after 24 hours of her receipt of the DTaP vaccine. In his opinion, "her parents would not have sat at home with an infant who is not moving her legs for 7 days," since that would have resulted in "Sarah Martinez sitting at home with a . . . paraplegic infant for days before seeking medical attention . . ." Tr. at 208–09; Willer Third Rep. at 6; Willer Fourth Rep. at 2. When confronted (during cross-examination) with the fact that Petitioners *did* seek medical attention shortly after vaccination, Dr. Willer speculated that treaters like Dr. Stewart would not have ignored obviously-neurologic symptoms. Tr. at 209.

More broadly, Dr. Willer admitted that he could not identify medical record evidence to corroborate his contention that W.M. had *not* likely experienced TM-associated symptoms sooner than July 1. Willer Third Rep. at 3. But he maintained nevertheless that the totality of the record suggested an earlier onset was unlikely. Tr. at 136–66. W.M.'s behavior shortly after and in the days following vaccination, for example, was in Dr. Willer's view simply evidence she was experiencing a common form of nonspecific reaction to vaccination. *Id.* at 136–38; DTaP Package Insert at 1, filed as Ex. 78 on Nov. 12, 2021 (ECF No. 85-6) (stating that "systematic reactions that occurred in [less than] 50 percent of subjects following any dose included fussiness/irritability, inconsolable crying, and decreased activity/lethargy"). W.M.'s twin sister also initially experienced a similar nonspecific, malaise-like reaction, featuring lethargy and fussiness. Tr. at 136–37, 150–51, 198. However, the twins' symptoms began to diverge not long after. *Id.* at 137.

[14] Dr. Willer also quibbled with the inclusion of "hypotonic" as a symptom the Petitioners purportedly reported to treaters at this time. He deemed it unlikely that a parent would use such a medical term unless they had previous experience with some kind of disabled child. Tr. at 143, 192–93. I take Dr. Willer's point, but also find it likely that in recording W.M.'s history, the treater who took down this note likely substituted the medical term for a more generalized description the Petitioners had provided—and thus do not find (as Dr. Willer is seeming to suggest) that the use of the term is an outright impossibility (even though it is in fact unlikely the Petitioners used it specifically).

Dr. Willer further challenged Dr. Lazari's progress note[15] regarding W.M.'s course (which if accurate would suggest an onset before July 1, and likely far closer to vaccination). Tr. at 161–62, 164; Ex. 10 at 24. Dr. Lazari's notes were, in Dr. Willer's estimation, illogical, since they described circumstances in which W.M. had progressed rapidly, experienced no symptoms development for two to three day, and then underwent a downward course symptomatically thereafter. Tr. at 163, 200–01, 220; Willer Fourth Rep. at 2. If in fact W.M. had been experiencing TM's progression starting on an earlier date, then she should have reached nadir sooner than what the record actually suggested had occurred.[16] Tr. at 150, 163–64, 197, 200–05, 220; Willer Third Rep. at 3, 6.

In addressing the above, Dr. Willer acknowledged inconsistencies between the medical records and the Petitioners' testimony or witness statements regarding onset and the nature of the symptoms they observed, and admitted they had provided histories of W.M.'s health that (in some cases) suggested an earlier onset. Tr. at 195–96; Willer Second Rep. at 3, 6; Willer Fourth Rep. at 2. But he deemed the Petitioners' descriptions during the hearing more reliable than the medical records made closer in time to W.M.'s injury. Tr. at 198; Willer Third Rep. at 6; Willer Fourth Rep. at 2. And Dr. Willer otherwise considered some histories or symptoms descriptions simply to be unlikely, for the reasons mentioned above. Tr. at 195–98; Willer Fourth Rep. at 2.

Although Dr. Willer deferred to his co-expert, Dr. Gershwin, on the larger issues of causation, he briefly addressed whether epidemiologic evidence could discount the possibility of causation. Tr. at 181–84; Willer Third Rep. at 4. Dr. Willer argued that studies with enough statistical power to prove a causative relationship between vaccines and TM were not possible. Tr. at 181; Willer First Rep. at 3; Willer Second Rep. at 3–4; Willer Third Rep. at 1. Most epidemiologic evidence was, therefore, not useful in assessing causation with respect to a rare disease like TM. Tr. at 181.

In the course of this testimony, Dr. Willer referenced a study that seemed to discount a Tdap-TM relationship. R. Baxter et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis*, 63 Clinical Infectious Diseases 1456, 1456–61 (2016) filed as Ex. 27 (ECF No. 32-7) ("Baxter"). Baxter found no increased risk for TM in association with *any* vaccine, including the DTaP vaccine. Baxter at 1456–61. Out of 64 million vaccinations considered, Baxter's authors

[15] Besides the content of this record, Dr. Willer maintained that Dr. Lazari was merely an intern, increasing the likelihood that the history he had provided was inaccurate. Tr. at 210–14, 221; Willer Third Rep. at 3, 6; Willer Fourth Rep. at 2. In addition, he argued that electronic medical record-keeping often resulted in the automatic repeat of older histories in subsequent records, and thus could maintain error over time. *Id.* at 212–214. While these contentions are not without merit, I also do not find that they provide more than a speculative basis for doubting the accuracy of the record at issue—since the Dr. Lazari notes *themselves* have not been established to be likely in error (whether because of his experience or for some other reason).

[16] During cross examination, Dr. Willer did admit that nadir can occur between 4 hours (though he corrected it was more like 4 days) to 21 days following symptom onset. Tr. at 129, 132–33, 178, 203; Willer First Rep. at 4.

observed approximately 81 cases of acute-onset TM—but only 67 of those cases reported vaccination within nine months prior to the onset of symptoms, one of which occurred after DTaP (out of approximately 1.7 million doses administered for the studied subjects). *Id.*; Willer First Rep. at 5; Willer Second Rep. at 4; Baxter at 1459–60. Despite the facially large number of vaccination events at issue, Dr. Willer maintained Baxter was too underpowered to rely upon. Tr. at 181–84; Baxter at 1456–61; Willer Second Rep. at 4. And if it were credited, Baxter would essentially indicate that vaccines could help *prevent* TM, since the infections they targeted were more likely causal of TM in most cases. Tr. at 184; Willer First Rep. at 4; Willer Second Rep. at 4. But this did not rule out the possibility of vaccine causation completely. Willer Third Rep. at 4. Until a study could eliminate the effect of the vaccine decreasing the risk of preventing the infection, or could reliably focus on such rare diseases, case reports remained, in Dr. Willer's view, the best evidence to assess causation. Tr. at 223–25.

2. *Eric Gershwin, M.D., MACR, MACP* – Dr. Gershwin, a board-certified immunologist with expertise in internal medicine, rheumatic disease, allergy, and immunology, submitted an expert report and testified for the Petitioners, offering the opinion that the DTaP vaccine can cause TM. *See generally* Tr. at 228–304, 525–36. Report, dated July 27, 2020, filed as Ex. 35 (ECF No. 64-1) ("Gershwin Rep.").

Dr. Gershwin received his undergraduate degree from Syracuse University, his medical degree from Stanford University, and his graduate degree from the Centre for Astrophysics and Supercomputing. *See* Curriculum Vitae, filed July 27, 2020 (ECF No. 64-2) ("Gershwin CV"), at 1; Tr. at 228. He completed his internship and residency at Tufts New England Medical Center, and two fellowships in rheumatology and allergy/immunology at the National Institutes of Health. Gershwin CV at 2; Tr. at 229. He is currently employed as chief of the Division of Rheumatology and Clinical Immunology and professor of medicine at University of California at Davis ("UC Davis"). Gershwin CV at 1; Tr. at 230. Dr. Gershwin is licensed to practice medicine in California and is board certified in allergy and immunology, rheumatology, and internal medicine. Gershwin CV at 2; Tr. at 229. Dr. Gershwin also publishes extensively and is well researched in epidemiological studies. Tr. at 231–33, 265. He has also seen 25 to 50 TM patients. *Id.* at 239. He currently serves as the editor of the *Journal of Autoimmunity, Clinical Reviews in Allergy, Autoimmunity Reviews, and Reviews in Autoimmunity*. Gershwin CV at 5.

Dr. Gershwin only briefly reviewed TM's characteristics, stating that Dr. Willer's testimony adequately set forth the nature of the injury. Tr. at 238–39. He described TM as a rare immunological or inflammatory disease, with a prevalence of one to eight per million people (even rarer if individuals with MS or other diseases, whose presenting symptom was TM, are excluded). *Id*. at 239–40; Gershwin Rep. at 2, 6. TM more frequently occurs in adults rather than children. Tr. at 240. Dr. Gershwin spent a great deal of time deciphering the question of how one explains an immune response that is localized to a limited area of the spinal cord, versus one that affects the entire spinal column (longitudinally). Tr. at 239; Gershwin Rep. at 2. In Dr. Gershwin's view,

there had to be something unique at the local microenvironment level for TM to occur focally—although far more medical and scientific research would be needed to understand what might explain this process. Tr. at 239–40, 287; Gershwin Rep. at 2–3.

W.M.'s TM, Dr. Gershwin maintained, was most likely caused by the DTaP vaccine. He discussed several points in the medical record that he believed supported this conclusion. Tr. at 236, 268; Gershwin Rep. at 9. In particular, the record provided no evidence of a genetic predisposition, environmental trigger, or immunological insult other than vaccination. Tr. at 237; Gershwin Rep. at 2, 10. And as of the date of the hearing (approximately eight years after the injury), there was no evidence of another autoimmune neurologic disease either. Tr. at 248. This left only the vaccine as likely causal. *Id.*

Dr. Gershwin opined that molecular mimicry was the most applicable mechanistic explanation for how the DTaP vaccine could result in TM. Tr. at 237, 247, 277; Gershwin Rep. at 9. As he explained, a foreign antigen (specifically the amino acid sequences that comprise its proteins), can sometimes resemble a protein structure found in the person's body. Tr. at 243; Gershwin Rep. at 8. Thus, in addition to provoking an immune response, antigens in a vaccine can cause a cross-reaction in which antibodies produced in reaction to the vaccine attack self tissues (here, the spinal cord). Tr. at 242–43, 258. This occurs in the context of inflammation (featuring a variety of infiltrating T cells, B cells, and other monocytic population) that leads to local nerve damage. *Id*. at 258, 302. Molecular mimicry ultimately involves homology between presenting antigen and self-antigen—a process that is extremely difficult to study or observe scientifically, no matter its reliability as a theory. *Id*. at 246–47, 278; Gershwin Rep. at 8; Palatnik-de-Sousa et al., *Editorial: Epitope Discovery and Synthetic Vaccine Design*, 9 Frontiers in Immunology 1, 1–2 (2018), filed as Ex. 71 (ECF No. 80-8).

Dr. Gershwin next expanded upon how the innate and adaptive immune responses impact the mechanism of molecular mimicry, leading to an autoimmune process causal of disease like TM. Tr. at 280; Gershwin Rep. at 7, 9. Molecular mimicry occurs as part of the adaptive immune response (since the antibodies critical to the theorized cross-attack do not come into being until this phase of an immune reaction), and thus is preceded by the more-immediate innate response. Tr. at 280–81, 301. After vaccination, the innate, largely-nonspecific reaction (which is often deemed the "humoral" phase)[17] occurs first, mediated by cytokines. Then, as the immune response continues, shifting toward the memory-oriented adaptive response, IgM antibodies respond, followed later by a more specific IgG response,[18] in which resident immune cells within the spinal

[17] *Humoral,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=23202 (last visited Sept. 9, 2022).

[18] IgM and IgG are antibodies produced in response to infection, and their titer levels can help monitor or detect immune deficiencies. *See Immunoglobulins (IgG, IgA, and IgM), Serum*, Mayo Clinic Med. Laboratories, https://www mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/8156 (last accessed August 22,

column and the cells that are stimulated by the antigen begin the adaptive focal attack on spinal cord nerves and tissue. Tr. at 287–89; Gershwin Rep. at 3.

Dr. Gershwin was able to marshal little in the way of direct scientific or medical literature evidence to support a TM-DTaP association. At most, he referenced a recent article specific to the COVID-19 vaccine, arguing that it showed how vaccination could theoretically stimulate a molecular mimicry-driven autoimmune process. Tr. at 255–57; E. Khan et al., *Acute Transverse Myelitis Following SARS-CoV-2 Vaccination: A Case Report and Review of the Literature*, J. Neurology 1, 1–5 (2021), filed as Ex. 65 (ECF No. 80-2) ("Khan") (reporting a case of TM after receipt of a COVID-19 vaccination). He otherwise emphasized case reports. Tr. at 271; Gershwin Rep. at 5–6. Agmon-Levin, for example, gathered 37 case reports of TM following vaccination—although only five involved diphtheria and tetanus-containing vaccines. Tr. at 271–73; Agmon-Levin at 1200. And Dr. Gershwin also admitted that existing epidemiological evidence, such as Baxter, did not establish any association between vaccination and TM, but (echoing Dr. Willer) maintained that such studies, even when seemingly quite large, lacked the power to reliably detect such a rare disease (although comparable studies supporting causation have in the Program also been relied upon). Tr. at 272–73, 303; Gershwin Rep. at 2, 6.[19]

Besides attempting to affirmatively support his opinion, Dr. Gershwin took issue with a number of rebuttal points raised by Respondent's primary causation expert, Dr. Moy. First, he denied that damaging autoimmune disease processes could only occur in the context of an ongoing infectious process (which would include substantial cell damage propagated directly through infection that would in turn expose more self-antigens to the immune system, promoting autoimmune cross-reactions as a result). Tr. at 528, 533–34. Dr. Gershwin argued that Dr. Moy's literature used to support this argument was not peer reviewed. *See* M. De Martino et al., *Vaccines and Autoimmunity*, 26 Int'l J. of Immunopathology and Pharmacology 283, 283, 288 (2013), filed as Ex. I-3 (ECF No. 72-4) ("De Martino") (editorial reporting the existence of strong evidence of the role of infection in the development of autoimmunity, and it was unlikely that vaccines alone

2022). Although Dr. Gershwin characterized IgM as an element of the body's innate immune response (Tr. at 259, 281–82), this is somewhat imprecise. IgM is better understood as a nonspecific, fast-developing "natural" antibody that bridges the immune response between the immediate innate and subsequent adaptive phases, with the latter being the phase in which antibodies specific to an antigen (or, as Dr. Gershwin proposes, capable of cross-reacting with a self-structure that mimics the antigen that caused the antibody to generate in the first place) come into being and cross-react as part of an autoimmune process. IgM's presence is believed to suggest an existing infection, whereas IgG reveals a resolved, prior infection (since IgG antibodies are more specific and generate later in the immune process).

[19] On cross examination, Dr. Gershwin was asked, in effect, whether this criticism could be equally applied to studies that *support* causation, and in the context of equally rare diseases. *See, e.g.*, Tr. at 274-75; L. B. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States 1976-1977*, 110 Am. J. Epidemiology 105, 105 (1979), filed as Ex. I-7 (ECF No. 72-8) ("Schonberger") (looking at the rates of GBS after the 1977 flu season, where they looked at 45 million doses and found a correlation between an increased incidence of GBS following vaccination). He argued in response that such a study still could not be read as "100 percent proof" of causation, although he went on to maintain that Schonberger was more reliable than Baxter for several reasons specific to their distinguishable methodologies. Tr. at 274–75

are a significant source of autoimmune diseases, although vaccines could theoretically trigger autoimmunity). And Dr. Gershwin maintained that if cell damage alone was so critical to sparking an autoimmune response, then burn victims should be routinely experiencing secondary autoimmune disease. Tr. at 528.

Another argument advanced by Dr. Moy (that Dr. Gershwin briefly mentioned) was that the blood-brain barrier would likely prevent antibodies generated in response to the DTaP vaccine from crossing into the spinal cord. Tr. at 266–67, 528–29; Moy Rep. at 7. Dr. Gershwin argued that Dr. Moy lacked literature support for this assertion, adding that not enough was yet known about how the blood-brain barrier functioned to reach any conclusions about such matters, or even if the blood-brain barrier was involved in this immune response. Tr. at 266, 290–91. Crossover between the blood and the brain did occur, as proved in the case of fetuses in gestation. *Id*. at 266–67, 290–91, 528–29.

Dr. Gershwin did not deem meaningful the fact that W.M.'s twin did not develop post-vaccination TM. Tr. at 248–50. First, he noted that often twins were mistakenly thought to be identical genetically, when that contention had not been medically confirmed (and thus it could not be assumed that both twins in this case had the precisely same immune systems). *Id*. at 249. Although it was noted in the medical records that W.M. and R.M. had shared a placenta, it can be difficult to determine whether twins are identical without tissue typing. *Id*. at 294–95; Ex. 3 at 100. Second, the immune responses of twins are *known* to be distinguishable. Tr. at 250, 267, 526–27, 532–33. Somatic mutation, recombination, and transposons make immune responses unique, so it was hardly surprising that W.M. developed TM while her twin did not. *Id*. at 276, 295–97, 526–27, 532–33.

Regarding onset, Dr. Gershwin deferred to Dr. Willer's proposed date of July 1—but added that onsets slower or faster[20] would still be consistent with his causation theory. Tr. at 237–38, 240–41, 259, 268, 300; Gershwin Rep. at 2, 9. A more abrupt onset (between 24-48 hours) would suggest an innate immune mechanism's involvement—likely a localized IgM response leading to the chronic inflammation characteristic of TM.[21] Tr. at 237–38, 259, 281; Gershwin Rep. at 7–9; D. M. Herrin et al., *Comparison of Adaptive and Innate Immune Responses Induced by Licensed*

[20] Dr. Gershwin stated that it was unlikely onset would begin *within* 24 hours, but 24-48 hours was appropriate. Tr. at 298; Gershwin Rep. at 9.

[21] Serum IgM, Dr. Gershwin maintained, could appear within a few days of symptoms following an infection. Tr. at 251–52, 259, 281–84; Gershwin Rep. at 2–3, 9. Maternal IgG is still present in newborn infants, so if an onset of TM was found within a shorter timeframe—24 hours—those innate immune mechanisms would likely be involved. Gershwin Rep. at 9; A. Haider, *Serum IgM in Diagnosis of Infection in the Newborn*, 47 Archives Disease in Childhood 382, 382–83, 392–93 (1972), filed as Ex. 37 (ECF No. 64-3) (infants start to produce their own immunoglobins as the maternal immunoglobins start to fade); C. Herve et al., *The How's and What's of Vaccine Reactogenicity*, 4 Nature Partner J. Vaccines 38, 38–40 (2019), filed as Ex. 60 (ECF No. 66-6) (noting that within hours of vaccination, inflammatory molecules are produced in the sera, and it does not stay localized to the injection site). But Dr. Gershwin maintained that he ultimately relied on, and accepted, the onset timeframe proposed by Dr. Willer. Tr. at 237–38.

Vaccines for Human Papillomavirus, 10 Hum. Vaccine Immunotherapy 3446, 3446–52 (2014), filed as Ex. 59 (ECF No. 66-5). Since the vaccination at issue was W.M.'s third DTaP dose, the time to mount a significant immune response would inherently be shorter. Tr. at 292; Gershwin Rep. at 3.[22] Alternatively, onset could reasonably occur days later (up to two to three weeks). Tr. at 259. If so, it would reveal that the IgM response had evolved to IgG antibodies. Tr. at 238, 259, 292; Gershwin Rep. at 3. He deemed Agmon-Levin (which revealed a variety of case study instances of onset), plus another article specific to the COVID-19 vaccine, as supportive of his overall timing opinion. Tr. at 241, 253–54; Gershwin Rep. at 9; Agmon-Levin at 1200, 1202 (standing for the fact that individuals had an onset of TM within days of vaccination); M. Khayat-Khoel et al., *Covid-mRNA Vaccination Leading to CNS Inflammation: A Case Series*, J. Neurology 1, 1, 11 (2021), filed as Ex. 64 (ECF No. 80-1) (citing to neurologic symptomatology following COVID-19 vaccinations between 1-21 days).

B. Respondent's Experts

1. *Timothy Lotze, M.D.* – Dr. Lotze, a pediatric neurologist, testified on behalf of Respondent, and submitted three expert reports. *See generally* Tr. at 310–445; Report, dated Apr. 24, 2018, filed as Ex. A (ECF No. 35-1) ("Lotze First Rep."); Report, dated July 17, 2019, filed as Ex. C (ECF No. 49-1) ("Lotze Second Rep."); Report, dated July 29, 2020, filed as Ex. D (ECF No. 68-1) ("Lotze Third Rep."). Dr. Lotze largely focused his opinion on what might constitute W.M.'s TM onset—and whether the vaccine could be implicated in the timeframe he favored.

Dr. Lotze obtained his bachelor's degree from Texas A&M University in College Station, Texas, followed by his medical degree at the University of Texas, San Antonio. *See* Curriculum Vitae, filed as Ex. B (ECF No. 35-2) ("Lotze CV") at 1; Tr. at 311. Thereafter, he completed two residencies and an internship at The Ohio State University finishing his education with a residency in Child Neurology at Baylor College of Medicine in Waco, Texas. Lotze CV at 1; Tr. at 311. He was then hired as a faculty member at the Baylor College of Medicine, where he is currently employed. Lotze CV at 1; Tr. at 311. He also serves as the Director for the pediatric multiple sclerosis clinic, fellowship program for pediatric multiple sclerosis and neuroimmunology, and neuromuscular program at Texas Children's Hospital. Tr. at 312. He is board certified by the American Board of Pediatrics and the American Board of Psychiatry and Neurology, with a special qualification in child neurology. Lotze CV at 2; Tr. at 311. He has also published close to 100 articles of peer-reviewed literature. Tr. at 314.

[22] On cross examination, however, Dr. Gershwin admitted that W.M. had not experienced any adverse reaction to the prior doses—thus reducing the reliability of any argument that she had demonstrated "rechallenge" to the dose at issue. Tr. at 292–93; *see generally Nussman v. Sec'y of Health & Hum. Servs.*, No. 99-500V, 2008 WL 449656, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2008), *aff'd,* 83 Fed. Cl. 111 (2008) (defining challenge-rechallenge as "when a person (1) is exposed to one antigen, (2) reacts to that antigen in a particular way, (3) is given the same antigen again, and (4) reacts to that antigen similarly").

Dr. Lotze agreed with Petitioners' experts that W.M. was accurately diagnosed with TM.[23] Tr. at 318, 387; Lotze First Rep. at 3. TM, an autoimmune disease, typically manifests with weakness in the lower extremities plus evidence of bowel issues, and can be confirmed with MRI studies. *Id.* at 318, 325, 445. Dr. Lotze also noted that TM can be classified as partial or complete,[24] depending upon the degree of symptoms and severity of impairment. *Id.* at 319–20, 326, 378. In infants, TM can appear as a regression in motor skills and development, change in bowel or bladder habits, and irritability—all of which W.M.'s medical records support occurred in this case. *Id.* at 376, 378. W.M.'s TM initially presented with decreased tone, weakness, and movement, followed by *increased* tone and movement in the affected limbs as underlying inflammation resolved.[25] *Id.* at 324–27, 378; Lotze Third Rep. at 2; V. L. Wolf et al., *Pediatric Acute Transverse Myelitis Overview and Differential Diagnosis*, 27 J. Child Neurology 1426, 1428 (2012), filed as Ex. F (ECF 68-3) ("Wolf").

Dr. Lotze also noted that TM can either reflect the existence of a greater neurologic condition or be a monophasic singular occurrence. Tr. at 445. In the context of disease-related TM (for example, TM as a presenting symptom of some greater neurologic inflammatory injury), the primary pathogenic driver is a specific antibody that causes the initial symptoms, whereas TM in other contexts is attributable simply to immune system factors. *Id.*; Lotze First Rep. at 3. Disease-associated TM less commonly occurs in infants, whose TM is more often deemed idiopathic. Tr. at 319–22, 420; Lotze First Rep. at 3; Absoud et al., *Pediatric Transverse Myelitis*, 87 Neurology S46, S47 (2016), filed as Ex. A-1 (ECF No. 82-1) ("Absoud") (noting that the majority of children with TM have an unknown cause to the disease); Wolf at 1428 (highlighting that idiopathic acute TM can account for up to 89 percent of cases in pediatric studies). Dr. Lotze agreed that TM was a rare disease generally, but deemed idiopathic TM relatively common in a pediatric population. Tr. at 322–23.

[23] Dr. Lotze specifically characterized W.M.'s condition as idiopathic, partial TM, of an unknown origin and unrelated to her DTaP vaccine receipt. Tr. at 331, 420-25; D. M. Wingerchuk & B. G. Weinshenker, *Acute Disseminated Encephalomyelitis, Transverse Myelitis, and Neuromyelitis Optica*, 19 Continuum 944, 953 (2013), filed as Ex. 21 (ECF No. 32-1).

[24] The key difference between partial and complete TM is the degree of cord injury as well as symmetry of symptoms. Tr. at 328–29. In partial TM, tonic spasms—which Dr. Lotze defined as episodic events involving the extension, stiffening, and subsequent relaxing of the legs—are more common. *Id.* at 325, 330

[25] On cross examination Dr. Lotze explained the differences between hypotonicity, hypertonicity, and spastic paraparesis in the evolution of TM symptoms. Tr. at 378–86. He defined hypotonicity as a complete absence or decrease from the normal amount of muscle tone, which is often described by patients as limpness or floppiness. *Id.* at 378–79, 439–440. Hypertonicity is the opposite end of the spectrum, generally described as stiffness or resistance to passive movements. *Id.* at 379, 382. The normal progression in TM is an evolution from hypotonicity to hypertonicity. *Id.* at 379, 385. Spastic paraparesis refers to upper motor neuron findings of stiffness in the legs, often discussed as spasticity. *Id.* at 383. Spastic paraparesis typically occurs in the context of hypertonicity. *Id.* at 383–84.

Although he did not act as Respondent's primary causation expert, Dr. Lotze denied that TM could reasonably be associated with vaccination, noting an absence of medical or scientific literature connecting the two. Tr. at 331–33, 366–67, 370–73 (deferring to Dr. Moy on questions involving immunology); Lotze First Rep. at 4; Lotze Second Rep. at 3; Lotze Third Rep. at 3; K. Stratton et al., *Adverse Effects of Vaccines: Evidence and Causality* 542, 547–48 (Committee to Review Adverse Effects of Vaccines et al. 2012), filed as Ex. A-2 (ECF No. 82-2) ("IOM Rep.") (finding insufficient evidence to assess any connection between vaccines and TM); T. Rasmussen et al., *Use of Population Based Background Rates of Disease to Assess Vaccine Safety in Childhood and Mass Immunisation in Denmark: Nationwide Population Based Cohort Study*, British Med. J. 1, 1, 3 (2012), filed as Ex. A-3 (ECF No. 82-3) ("Rasmussen") (looking at 2.3 million infants and 37 million persons and observing only two cases of TM for every 100,000 people occurring within 7-42 days, thus calling into question the relationship between vaccinations and TM); Baxter at 1459–61.

Although Dr. Lotze admitted that TM's rarity made it harder for studies to determine its vaccine-associated risk with any degree of certainty, he maintained that studies like Rasmussen and Baxter were scientifically reliable. Tr. at 367–70. By contrast, he criticized the probative value of case reports as causation evidence. Tr. at 335–39. Agmon-Levin, for example, was little more than the results of an internet search for publications addressing TM after vaccination—and its authors did not establish that they had thoroughly reviewed each article to confirm that the alleged instances of TM met any common or accepted diagnostic criteria, or ensured that the TM cases were good comparables.[26] *Id.* at 334–35, 337; Lotze Second Rep. at 2.

Two of the specific case studies out of the 37 relevant instances identified in Agmon-Levin were illustrative of the article's unreliability. For example, one involved a case of TM where Agmon-Levin reported that onset occurred within two days after rabies vaccination, but according to Dr. Lotze the underlying case at issue revealed that onset was actually *seven* days[27] later. Tr. at 335–36; Lotze Third Rep. at 3; L. Label & D. Batts, *Transverse Myelitis Caused by Duck Embryo Rabies Vaccine*, 39 Archives Neurology 426, 426 (1982), filed as Ex. G (ECF No. 68-4) ("Label"). In addition, the Label patient had an infected wound—an alternative cause for TM given no weight by Label's authors (or Agmon-Levin's for that matter). Tr. at 30; Label at 426. In another, the case report's authors expressly disclaimed confidence in whether the relevant vaccine (rubella) had been causal, noting that the patient's presenting TM symptoms may have been impacted by his

[26] Dr. Lotze contrasted Agmon-Levin with Baxter, noting that Baxter's authors used reasonable diagnostic criteria for TM and rigidly applied them to the cases they considered. Tr. at 334.

[27] Label actually noted that TM occurred even later (within *eleven* days of the rabies vaccination). Label at 426 (noting that in 1979, "transverse myelitis developed in a 50-year-old man 11 days after passive and actives rabies immunization.").

dysplasia.[28] Tr. at 336–37; Lotze Third Rep. at 3; S. Holt et al., *Diffuse Myelitis Associated with Rubella Vaccination*, 2 British Med. J. 1037, 1037–38 (1976), filed as Ex. H (ECF No. 68-5).[29]

The record in this case, Dr. Lotze maintained, did not support the conclusion that the DTaP vaccine had caused W.M.'s TM.[30] Tr. at 361. In so opining, he deemed the contemporaneous medical records for W.M.'s treatment more accurate than subsequent witness statements. *Id.* at 355, 399. This was especially so since W.M. had been hospitalized at a teaching hospital, where multiple interviewers are likely to interact with patients or their guardians.[31] *Id.* at 339–40. Dr. Lotze also highlighted record evidence that he felt underscored the possibility of post-infectious TM. In particular, W.M. had been reported to be experiencing a low-grade fever, and displayed enlarged lymph nodes, shortly after vaccination. *Id.* at 341–43, 424; Lotze First Rep. at 4. Some antecedent infections were known triggers of TM. Tr. at 357–58. At the same time, however, the fever had occurred in the wake of vaccination, and W.M.'s parents did not recall any prior illness, so the absence of lab testing for a potential viral cause made it difficult to corroborate this possibility. *Id.* at 342–43, 424. And Dr. Lotze admitted that some of W.M.'s treaters had discussed the possibility of a vaccine reaction, although he was ultimately unpersuaded by their reasoning. *Id.* at 426–27; Ex. 10 at 24.[32]

Dr. Lotze next offered several comments on W.M.'s purported onset—and specifically whether it had occurred when Dr. Willer maintained, or far closer in time to vaccination. As a general matter, he proposed that TM's symptoms would have evolved over the course of a two-to-four-day timeframe. Tr. at 323–24, 386; Lotze Third Rep. at 2; Absoud at S47 (listing an onset date between two to four days). Thus, although the range of a few hours to 28 days for reaching

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[28] Dysplasia is an abnormality of development. *Dysplasia,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15275&searchterm=dysplasia (last visited Sept. 9, 2022).

[29] Dr. Lotze also mentioned Khan (a case report already deemed not all that probative, since it involved the COVID-19 vaccine), finding it unlikely that TM symptoms would begin within 24 hours of vaccination. Tr. at 337–38; Khan at 2.

[30] Dr. Lotze did not, however, give much weight to the fact that the Martinez twins had not both experienced TM. It is not uncommon for one child to present with an illness while a sibling does not. Although siblings—especially twins—go through similar experiences, there are differences in their environmental exposures, and therefore it cannot be assumed that they will in all cases suffer the same injuries. Tr. at 344–45.

[31] Dr. Willer's supposition that unskilled or inexperienced treaters would more likely make errors in their notes was rejected by Dr. Lotze. In his experience, the faculty in a teaching hospital context would take steps to ensure the accuracy of recorded facts about medical histories or treatments. Tr. at 340–41.

[32] The issue of whether the blood-brain barrier might prevent an aberrant immune response (by preventing immune cells from attacking the spinal cord) was briefly considered by Dr. Lotze. He described the blood-brain barrier as a unique biological structure known to make it hard for certain pathogens (and even drugs) get through to the central nervous system. Tr. at 338–39. Evidence that would establish whether the blood-brain barrier had been breached would include neurologic problems, such as weakness in the legs, sensory disturbances, and bowel impairments if the breach occurred in the spinal cord. *Id.* at 442–44.

nadir, as described by Drs. Willer and Gershwin, had some utility in differentiating a case of TM from other kinds of disease processes, TM most typically would occur (in Dr. Lotze's experience) over a tighter timeframe of around five to six days after onset.[33] Tr. at 327–28, 356, 429, 437; Lotze Third Rep. at 2.

The relevant medical record revealed that in W.M.'s case, TM onset had most likely occurred within 24 hours (between June 26-27) of her vaccination, with nadir arriving four days later—a timeframe Dr. Lotze deemed not medically reasonable for causation under the circumstances. Tr. at 345, 353, 438; Lotze First Rep. at 3; Lotze Second Rep. at 1. To support this aspect of his opinion, Dr. Lotze provided a detailed review of W.M.'s medical history.

First, Dr. Lotze noted the concerns expressed on the evening of June 26 (the same day as vaccination) when W.M. was not rolling around, which raised the possibility of the manifestation of initial symptoms. By the following morning, she showed more certain indicators of TM, such as an inability to move her legs, then periodic stiffening on June 28, implying the beginning of abnormal movements and tonic spasms.[34] Tr. at 345–47, 353, 359–60, 388–92, 405; Lotze First Rep. at 3; Lotze Second Rep. at 1; Lotze Third Rep. at 1–2. Other notes from treaters corroborated that her symptoms had likely begun the same day as vaccination. Tr. at 346–48, 350, 435–37; Ex. 8 at 43–44 (reporting on July 1 from Dr. Griffin and NP Cawley that W.M. would not bear weight or move her legs, and that she was lethargic and hypotonic since vaccination); Ex. 8 at 54–55 (during a visit on August 1, 2013, Dr. Griffin disputed that W.M.'s symptoms were related to her vaccination, since they occurred no more than two days after the fact); Ex. 9 at 7 (indicating under history of present illness that after W.M. received her vaccination, her parents noticed irritability and lack of leg movement); Ex. 10 at 24 (reporting from Dr. Lazari that W.M. was "limp after shots,"); Ex. 10 at 62 (indicating in W.M.'s medical history taken by Dr. Strickland on July 3, 2013, that the night of W.M.'s vaccination, there was observed decreased tone in her legs, which thereafter were not moving over the following 48 hours); Ex. 10 at 149 (finding from a neurology visit on August 5, 2013, with Drs. Claudio-Sandoval and Carrol that W.M. developed lower extremity weakness within a few hours of her vaccination).

On cross examination, Dr. Lotze was asked about the absence of medical record evidence specifically from the 24-hour post-vaccination period, as well as the fact that none of the records used the word "weakness" to describe W.M.'s symptoms. Tr. at 388–91, 394. Dr. Lotze argued in

[33] Dr. Lotze specified that the timeframe to symptoms nadir is not differentiated between children and adults. Tr. at 328.

[34] Dr. Lotze contended that the description of periodic stiffening on June 28, 2013, did not necessarily imply there was hypertonicity, but actually tonic spasms, which can occur in the midst of the acute inflammatory process. Tr. at 405–06, 418, 430; Lotze First Rep. at 2. Although the word used in the record was "stiffening" and not "spasm," he did not find this necessarily signified hypertonicity. Tr. at 406–11; Ex. 10 at 24. As the stiffening was described as periodic, Dr. Lotze found it normal it was not mentioned in future visits, adding that this symptom could resolve with the progression of TM. Tr. at 412–13, 438–40; Ex. 8 at 44.

response that other descriptions (i.e., limp, decreased activity levels, "will not bear weight on legs") were *suggestive* of weakness even if that precise term had not been employed. Tr. at 388–90, 394, 397. Dr. Lotze also agreed that the DTaP package insert reports that infants may experience post-vaccination fatigue,[35] irritability, fever, and become inconsolable, and W.M.'s sister appeared to experience some of these symptoms shortly after vaccination, but he deemed these confounding variables. Tr. at 395–97, 431; DTaP Package Insert at 1. At bottom, the record in his reading revealed that W.M. was unable to move her legs on June 27, 2013—a distinguishable symptom from the post-vaccine reaction symptoms listed in the package insert. Tr. at 435; Lotze Second Rep. at 1.

Dr. Lotze was unable to offer comment on the findings from W.M.'s urgent care visit on June 29, 2013, since there were no medical records memorializing the event. In addition, it had been represented that W.M. was not taken out of her car seat during this treater visit, so a neurologic exam in such a position would make it impossible to identify features of TM. Tr. at 352–53. He also did not deem significant W.M.'s episode of constipation on June 30, 2013. While bowel issues are seen in the context of TM, they would not present immediately, but would instead be secondary to other symptoms and problems, like the weakness of abdominal muscles and an inability to bear down. *Id.* at 351–52, 416–18.

Dr. Lotze also felt that W.M.'s subsequent history was consistent with the onset he proposed. He highlighted Petitioners' testimony that W.M. began straightening and stiffening her leg following the July 1, 2013 visit, deeming this evidence that W.M. was by this point evolving into the next stage of TM, where weakness and low tone is replaced by spasticity, increased tone, and increased reflexes. Tr. at 348–49, 354–55. The subsequent July 3, 2013 visit to Dr. Park resulted in additional evidence of spasticity—and then W.M.'s hospital stay ultimately confirmed TM in a true neurologic exam. Ex. At 349–51; Ex. 9 at 7; Ex. 10 at 24. Thus, W.M.'s overall course was consistent with TM's usual evolution—but her onset close-in-time to vaccination did not permit the conclusion that the vaccine had caused it.[36] Tr. at 350, 543.

2. *James Moy, M.D.* – Dr. Moy, an attending physician specializing in allergy and immunology, testified on Respondent's behalf and prepared a written report, as well. *See generally* Tr. at 446–524; Report, dated October 16, 2020, filed as Ex. I (ECF No. 72-1) ("Moy Rep."). He sought to rebut Petitioner's argument that the DTaP vaccine can cause TM.

[35] There was much discussion at hearing regarding W.M.'s fatigue, and whether the medical records established that W.M. was fatigued or if it was something greater. Tr. at 431–32. Relying on the medical records, Dr. Lotze pointed out that W.M. was unable to move her legs on June 27, which is an indicator for TM rather than symptoms indicated on the package insert, whereas the Petitioners testified that W.M. was lethargic throughout her whole body, which fits more easily under the description of symptoms following vaccination. *Id.* Dr. Lotze relied on the medical records as better evidence of the contemporaneous facts. *Id.* at 432.

[36] Thus, Dr. Lotze found that Dr. Lazari's description of timing and sequence of events was likely correct, despite Dr. Willer's objections. Tr. at 359.

Dr. Moy received his undergraduate degree from Northwestern University and his medical degree from the University of Illinois College of Medicine. *See* Curriculum Vitae, filed as Ex. J on October 19, 2020 (ECF No. 72-9) ("Moy CV") at 1; Tr. at 446. Thereafter he completed his residency in pediatrics at the University of Minnesota and a fellowship in allergy/immunology at Rush University Medical Center. Moy CV at 1; Tr. at 446. Dr. Moy is currently an associate professor in the Departments of Immunology/Microbiology, Pediatrics and Internal Medicine, as well as the associate training program director for the allergy/immunology fellowship program, at Rush University Medical Center. Moy CV at 1; Moy Rep. at 1; Tr. at 447. He is board certified by the American Board of Pediatrics and the American Board of Allergy and Immunology. Moy CV at 2; Tr. at 447. Dr. Moy has also authored 60 publications in peer-reviewed journals in the areas of asthma, allergic reactions, medication side-effects and immunodeficiency diseases. Moy Rep. at 1; Tr. at 448. Since 1990, he has evaluated and managed over 300 pediatric, adolescent, and young adult patients with autoimmune diseases and disorders. Moy Rep. at 1.

Dr. Moy accepted W.M.'s TM diagnosis as substantiated by the medical record. Tr. at 452, 488. He also described TM's characteristics and etiology, explaining that TM is considered an immunological inflammatory disease, and is most often thought to be propagated by antibodies against nerve tissues on the spinal cord. *Id*. at 453; Moy Rep. at 5. TM is likely triggered by an inciting factor getting into the central nervous system. Tr. 489, 516. It most commonly occurs in a post-infectious context, but it can also be idiopathic—as in W.M.'s case, he proposed. *Id*. at 453.

Dr. Moy did not accept that TM could be vaccine-caused. First, he attacked the independent scientific evidence offered by Petitioner—primarily case reports, which he deemed poor evidence for causality. Tr. at 455, 507; Moy Rep. at 8; T. Nissen & R. Wynn, *The Clinical Case Report: A Review of its Merits and Limitations*, 7 BioMed Central Research Notes 1, 1, 4–5 (2014), filed as Ex. I-2 (ECF No. 72-3) (mentioning the occurrences in a case report cannot be generalized from one patient to the broader population, causality cannot be inferred from an uncontrolled observation, and temporal association does not imply a cause-and-effect relationship). Although Petitioners' experts had objected that the rarity of relevant evidence on the topic required giving case reports *some* consideration, Dr. Moy deemed epidemiologic evidence more probative. In support of this argument, he pointed to GBS (also a rare disease), noting that epidemiological studies were available to reliably establish an increased incidence of GBS following flu vaccination. Tr. at 456–57, 493–94; Moy Rep. at 8; L. B. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States 1976-1977*, 110 Am. J. Epidemiology 105, 105 (1979), filed as Ex. I-7 (ECF No. 72-8) ("Schonberger"). Here, comparable on-point studies were not supportive of the relationship, and they merited greater weight than case reports. Tr. at 456, 509–11, 521; Moy Rep. at 8; Baxter at 1456, 1461.

Second, Dr. Moy questioned molecular mimicry's value as a putative pathologic mechanism. Molecular mimicry is thought to occur when amino acid sequences constituting virus or bacteria antigenic proteins have homology[37] with amino acid sequences in the human body, resulting in a putative, immune cell-driven cross-reaction when antibodies to the antigen also attack homologous self-structures by mistake. But Dr. Moy maintained that whether molecular mimicry will actually result in an autoimmune disease process depends on whether the homology occurs in the context of an infection or vaccination.[38] Tr. at 461, 466–67, 495; Moy Rep. at 6. In Dr. Moy's view, an infectious process would tend to be more all-encompassing, not only stimulating an immune response (which vaccination seeks to "copy" to some extent) but also causing cell damage (as the replicating infection leads to cell death), which in turn would instigate the release of numerous self-antigens which could spark additional bases for autoimmune cross-reaction. Tr. at 497; Moy Rep. at 6.[39] He also noted that ample evidence establishes the role of infections in the development of autoimmune diseases—and even there, molecular mimicry is not always understood to be the relevant biologic mechanism driving the pathologic process. Tr. at 467–68; Moy Rep. at 6.

Dr. Moy also rejected Dr. Gershwin's contention that TM could arise as the product of an immediate, innate immune response (rather than the secondary, more immune memory-oriented adaptive response). Tr. at 475; Moy Rep. at 7. The innate response occurs first in reaction to a foreign antigen, and attempts to control an infection, leading to common symptoms of malaise (fever and muscle ache), whereas the adaptive immune system takes longer to ramp up, with B cells making antibodies and T cells killing viruses. Tr. at 461–62, 466. The process of molecular mimicry occurs during the adaptive response. *Id*. at 465, 483. The harm to the spinal cord caused by TM would more likely be the product of an auto-immune cross-reaction occurring during the latter, adaptive response, Dr. Moy argued.

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[37] Homology was defined as an identity between a portion of a protein from one organism and another. Tr. at 468; Moy Rep. at 6. But Dr. Moy maintained that homology alone is not enough to trigger molecular mimicry, because linear amino acid sequences are actually very common. Tr. at 468–69, 471. Otherwise, autoimmune diseases would be far more prevalent. *Id*. at 470.

[38] Of the potential reasons for these differences, vaccines—unlike infections—do not cause cell damage, which would release many more antigens from the human cells, increasing the likelihood of autoimmune reactions. Tr. at 497; Moy Rep. at 6.

[39] In support of this contention, Dr. Moy referenced De Martino—an editorial from a scientific publication arguing that although vaccines could theoretically trigger autoimmunity, there is no evidence that they tend to do so, given how different vaccination is from a wild infectious process. Tr. at 467–68, 514; Moy Rep. at 6; De Martino at 288. When cross-examined about the strength of the editorial's contentions, Dr. Moy proposed (somewhat unpersuasively) that editorials should carry more weight than case reports, since the former are not based solely on a single observed temporal instance of post-vaccination disease. Tr. at 522. While I deem Dr. Moy's argument on this topic to have some persuasive value—vaccination is inherently and contextually distinguishable from an infectious milieu—I also agree with Petitioners that an editorial item lacks the same probative value as an actual study, and therefore overall, I do not give these contentions the weight Respondent urges.

Another factor that limited the likelihood of vaccine-induced TM in Dr. Moy's view was the blood-brain barrier, which Dr. Moy noted can impede the crossing-over of immune cells into the central nervous system (the "CNS"). Tr. at 472, 518. The blood-brain barrier is semi-permeable, permitting only some substances to easily cross. *Id*. at 471; Moy Rep. at 7. Dr. Gershwin's theory was that the vaccine's antigen-presenting cells were carried into the CNS, and hence crossed the blood-brain barrier—yet, Dr. Moy maintained, there was no literature offered in this case establishing how immune cells can get into the CNS in the absence of an actual "break" in the blood-brain barrier. Tr. at 473, 475-76, 518. Thus, this fact also weighed against the likelihood of vaccination causing TM. *Id*.

Dr. Moy then raised three issues relevant to the medical record that he deemed strengthened his conclusion that vaccination did not likely cause W.M.'s TM. Moy Rep. at 8–9. First, Dr. Moy found significant that W.M.'s sister had not also developed TM post-vaccination. Tr. at 478. Since the twins likely shared the same genetics, their immune responses to the vaccine should have been identical, but were not, undermining the possibility that the vaccine itself was the causal factor. *Id.* He accepted the possibility that external environmental factors, or outright genetic mutation, could result in distinguishable immune systems between the two, but deemed the chance of mutation in this case low, given the twins' young ages. *Id*. at 476–78, 501, 523–24; Moy Rep. at 8. Indeed, Dr. Gershwin had assumed that the twins' initial vaccine-reactive malaise, which they both experienced, was common, underscoring why both should have also been harmed by the vaccine in the same way if it had the capacity to trigger TM. Tr. at 178–79.

Second, Dr. Moy took note of W.M.'s vaccination history. W.M. had received prior DTaP doses with no reaction, making it unlikely that the dose at issue had triggered autoimmunity where prior doses had not. *Id*. at 481, 499–500; Moy Rep. at 8. Finally, Dr. Moy noted a lack of evidence that W.M. had an infection or illness prior to vaccination. Although this fact could *rebut* the argument that an infection better explained W.M.'s TM (and indeed, Petitioners argue that no identified alternative cause exists), Dr. Moy found significant something else about a preexisting infection: that it might have had the secondary impact of causing the kind of blood-brain barrier weakening or breach that would be necessary to allow the antigen of antibodies to get across the CNS.[40] Tr. at 481–83, 490–92; Moy Rep. at 9. Since no infection that could have acted in this way had been identified, a blood-brain barrier breach was rendered more unlikely.

Dr. Moy concluded with some discussion of onset, largely relying on Dr. Lotze's opinion but providing some testimony relevant to the timeframes implicated in the two immune response arms. Tr. at 492. The innate response, he explained, occurs immediately and could last hours to a few days, whereas the adaptive response (measured by IgM at first) occurs within a few days and can last for 7-10 days, with IgG levels rising around 5-7 days later, and peaking around 3-4 weeks.

[40] Dr. Moy also noted, however, that it was possible to have an immune response to a pathogen that did not manifest in symptoms, similar to those unknowingly infected with COVID. Tr. at 518–19.

Id. at 462–63, 483, 486–87. A second exposure to an antigen would result in a somewhat faster adaptive immune response due to memory B cells, with the fastest response one day for IgM and 4-5 days for IgG. *Id*. at 484, 488.

Because of the foregoing (and regardless of literal onset date), it was implausible to Dr. Moy that the DTaP vaccine had caused W.M.'s TM given the facts in this case. Tr. at 503; Moy Rep. at 9. Even if the Tdap vaccine *could* be causal, the shorter onset favored by Dr. Lotze would require TM to spring up a day or two post-vaccination, despite an absence of independent evidence demonstrating that the innate response drives the inflammation characteristic of TM. Moy Rep. at 7. The onset favored by Petitioners (several days after vaccination) was no better, since the adaptive response that more likely is associated with TM would *only then* be starting to occur, and would also require certain secondary steps—crossing the blood-brain barrier, local production of IgG in the spinal cord, etc. *Id*. In effect, onset should have occurred *later* than what Petitioners alleged, given what was known about TM and the timeframes for the adaptive immune process.

III. Procedural History

Petitioners initiated this case in 2016, and the matter was at first assigned to another special master. ECF No. 1. Until late 2016, Petitioners continued to file medical records, and the case was in this period reassigned to another special master. Respondent then filed a Rule 4(c) Report on December 19, 2016, contesting Petitioners' right to compensation. ECF No. 18. The case was subsequently transferred to me before being reassigned (again) to another special master. ECF Nos. 26, 29. The parties began filing of expert reports, completing the process by the spring of 2020. The matter was finally transferred back to me on January 26, 2021, and I held a status conference with the parties, setting a two-day hearing to be held on November 16-17, 2021. ECF No. 77. The trial occurred as scheduled, and the parties submitted post hearing briefs on March 16, 2022. Petitioners' Post Trial Brief, dated March 16, 2022 (ECF No. 97) ("Post-Trial Br."); Respondent's Post Trial Brief, dated March 16, 2022 (ECF No. 98). The claim is now ripe for resolution.

IV. Applicable Legal Standards

A. *Petitioners' Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed.

Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[41] In this case, Petitioners do not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by

[41] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*.[42] *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the

[42] Because Petitioners have advanced the argument (primarily in their post-trial brief) that the actual prong one standard is *in fact* plausibility, I briefly discuss the merits of that contention in my prong one analysis below.

opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95

Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and

compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88

Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

ANALYSIS

I. TM as Vaccine Injury in Prior Program Decisions

The experts on both sides agreed that W.M. was properly diagnosed with TM, and this diagnosis finds ample record substantiation. Thus, resolution of this claim does not require determining the injury at issue.

Claims alleging TM following vaccination are common in the Vaccine Program. Many involve TM after receipt of the Hepatitis B vaccine. *See, e.g.*, *Pearson v. Sec'y of Health & Hum. Servs.*, No. 03-2751V, 2008 WL 5093378, at *3 (Fed. Cl. Spec. Mstr. Nov. 6, 2008); *Stevens v. Sec'y of Health & Hum. Servs.*, No. 99-594V, 2006 WL 659525, at *1, 8 (Fed. Cl. Spec. Mstr. Feb. 24, 2006). In *Pearson*, the special master found in the petitioner's favor, but did not identify the proposed causal theory at all, relying on the prior ruling from *Stevens*. *Pearson*, 2008 WL 5093378, at *3. And in *Stevens*, the petitioner successfully established causation on a theory of challenge/rechallenge after she had an adverse reaction to two doses of the Hepatitis B vaccine and subsequently developed TM. *Stevens*, 2006 WL 659525, at *1. As already noted, however, no such challenge/rechallenge evidence has been offered in this matter.

I also have granted entitlement in a case where an infant developed TM after receipt of the Hepatitis B vaccine. *McGrail v. Sec'y of Health & Hum. Servs.*, No. 17-926V, 2021 WL 1728706, at *25 (Fed. Cl. Spec. Mstr. Apr. 23, 2021). The petitioners in that case, as here, argued that molecular mimicry was the applicable mechanism. *McGrail*, 2021 WL 1728706, at *9, 11. However, I noted in *McGrail* that the petitioners' causation showing was not particularly robust, and thus an alternative outcome was possible in other cases, depending on the mix of evidence. *Id.* at *26. I also found that symptoms onset of 77 hours, or a little more than three days post-vaccination, was a medically appropriate timeframe. *Id.* at *27. While *McGrail* has some parallels to the present matter, it involved both a different vaccine and distinguishable onset—factors highly relevant to the outcome herein.

I have identified fewer cases involving TM after receipt of a Tdap/DTaP vaccine.[43] And their success or failure can turn on the timing of onset, as opposed to the causal capacity of the vaccine generally.[44]

[43] Claims alleging TM following a rotavirus vaccine alone are quite uncommon. Rather, this vaccine is usually one of several received at the same time (and such cases when successful have typically been the result of settlement rather than reasoned decision). *See, e.g.*, *Davis v. Sec'y of Health & Hum. Servs.*, No. 19-410V, 2022 WL 1469328 (Fed. Cl. Spec. Mstr. Apr. 19, 2022); *Martin v. Sec'y of Health & Hum. Servs.*, No. 16-318V, 2017 WL 6522406 (Fed. Cl. Spec. Mstr. Oct. 23, 2017); *Nichols v. Sec'y of Health & Hum. Servs.*, No. 11-417V, 2013 WL 599104, at *1 (Fed. Cl. Spec. Mstr. Jan. 22, 2013). However, because Petitioners' experts did *not* focus on rotavirus as the most likely causal vaccine, I do not evaluate it extensively herein.

[44] Petitioners' filings in this case highlight the fact that I recently issued (on remand, and after denying entitlement due to a failure to meet the first *Althen* prong) a favorable entitlement ruling for an adult petitioner alleging TM due

For example (and contrary to *McGrail*), I denied compensation in another case involving pediatric TM. *Palattao v. Sec'y of Health & Hum. Servs.*, No. 13-591V, 2019 WL 989380 (Fed. Cl. Spec. Mstr. Feb. 4, 2019). There, petitioners alleged that several vaccines—including DTaP—caused an infant's TM after an onset between 30-36 hours post-vaccination. I found, however, that the onset date was inconsistent with the proposed causation theory, occurring too close in time to vaccination for an adaptive immune response (which most likely characterized TM's pathogenesis) to have occurred. *Palattao,* 2019 WL 989380, at *34. I also determined that the *Palattao* petitioners had failed to establish that TM could be mediated by a cytokine-driven process occurring a part of the initial, innate immune response. *Id.* at *36. Petitioners' experts in *Palattao* had expressly rejected the theory of molecular mimicry (which was relied upon in this claim), proposing instead that the child's TM reflected an aberrant *innate* response driven by cytokines. *Id.* at *8. Although *Palattao* is clearly distinguishable in important respects, its findings about what is a reasonable onset timeframe for TM has relevance to this case, as well.

By contrast, timeframes for post-vaccination TM onset have often been deemed acceptable when the period of time between onset and vaccination exceeded a week. *See, e.g.*, *I.J. v. Sec'y of Health & Hum. Servs.*, No. 16-864V, 2021 WL 1232733, at *34 (Fed. Cl. Spec. Mstr. Jan. 4, 2021), *mot. for review granted on other grounds,* 155 Fed. Cl. 20 (2021) (TM beginning approximately two weeks after receipt of the Tdap vaccine); *Schmidt v. Sec'y of Health & Hum. Servs.*, No. 07-020V, 2009 WL 5196169, at *14 (Fed. Cl. Spec. Mstr. Dec. 17, 2009) (onset of TM one month after receiving the flu vaccine fell within a medically acceptable timeframe). These determinations are thus consistent with the view that a pathologic process driven by the adaptive response will not occur too close-in-time to vaccination.

to the Tdap vaccine. *I.J. v. Sec'y of Health & Hum. Servs.*, No. 16-864V, 2022 WL 277555, at *5–6 (Fed. Cl. Spec. Mstr. Jan. 4, 2022). But that petitioner prevailed mainly because I deemed the first *Althen* prong satisfied under the evidentiary standard of mere plausibility that had been embraced in that case by the Court's remand order. *I.J.* is otherwise not controlling of the outcome in this case, since it does not reflect a Federal Circuit determination (although, as discussed below, I do not find that the evidentiary standard it embraced was an accurate reflection of controlling precedent on the first prong).

II. Petitioners Have Not Carried Their Burden of Proof[45]

A. *Althen Prong Three*

The experts disagreed on the precise onset date, with Drs. Willer and Gershwin favoring a four-day post-vaccination onset (beginning on June 30, 2013), while Drs. Lotze and Moy proposed an onset occurring within 24 hours (beginning on the June 26 vaccination date). The record best supports Respondent's position, which is too close in time to have been caused by the vaccination (assuming the DTaP vaccine could cause TM) under the "medically acceptable" standard applied to timeframe issues in the Vaccine Program.

Numerous medical records from different visits substantiate that onset began within 24 hours of vaccination, or not appreciably long thereafter. Evidence of onset the morning after vaccination, or sometime that day, is found in records prepared by many treaters, including NP Cawley and Drs. Griffin, Lazari, Strickland, Claudio-Sandoval and Carrol. Ex. 8 at 43–44, 54–55; Ex. 9 at 7; Ex. 10 at 24, 62, 149. These records preponderantly establish clear concern for W.M.'s lack of leg movement as soon as *the day of* vaccination. In particular, the July 1, 2013, and July 3, 2013 records (the earliest treatment evidence in this case after the vaccination date) refer to leg issues "since" vaccination, or having "progressed" up to July 1—all of which reasonably suggests an onset *before* July 1. Ex. 8 at 43; Ex 9 at 7.

Then, subsequent records from W.M.'s hospitalization memorialize statements by the Petitioners (in recounting W.M.'s history) that they had observed leg-related symptoms by the morning of June 27—and these were the symptoms that later impelled them to seek treatment for W.M. (as opposed to her twin, whose initial vaccine malaise improved). *See* Ex. 10 at 24, 448. The record by itself is thus consistent in reporting neurologic-like symptoms prior to June 30—and closer to the morning of June 27. While these presenting issues cannot be neatly separated from the post-vaccination malaise that both twins appear to have experienced, it can be determined on this record that by June 27, 2013, W.M.'s leg issues had more likely than not manifested, and were notably distinguishable—enough to prompt Petitioners to seek care for W.M., and to express concerns that went beyond the fact that she was taking longer to recover from malaise than her twin.

Petitioners contest the accuracy of these records, or (via Dr. Willer) maintain that they are in some cases untrustworthy because a less-experienced treater prepared them (an argument I deem largely speculative). But they ultimately have not provided a persuasive reason to discount the

[45] I address the *Althen* prongs herein in order of their significance to my Decision, rather than in the order they are typically presented. I also include no detailed discussion of the second, "did cause" prong. My determination that W.M.'s onset was not medically acceptable for causation makes it impossible to find the vaccine was causal, even if there is some record evidence Petitioners might point to in support of the second prong, like treater speculation about vaccine causality.

overall contemporaneous record, which consistently points to an onset prior to June 30. Petitioners simply cannot simply gainsay these contemporaneous records, given the consistent picture they paint, and have provided no compelling reason to find their subsequent testimony or statements more credible. Petitioners also refer to the urgent care car seat "exam" with Dr. Stewart on June 29, arguing that it was more routine than reflective of concern about leg issues/spasticity. But not only was no record ever filed to document it (despite due effort by the parties), but this appeared to be a quick exam that cannot be deemed as substantively comparable to the full medical exams performed thereafter by W.M.'s other treaters. Indeed, the *fact itself* of this incident is somewhat supportive of the conclusion that by this time W.M.'s symptoms were alarming enough to seek additional treatment, thus bulwarking the inference that her neurologic symptoms had begun before early July.

I also do not give great weight to the argument that W.M.'s constipation was the presenting symptom of her TM on June 30. It simply cannot be concluded from the record that this was what drove Petitioners to bring W.M. to see treaters on July 1 or 3 (let alone why she was later hospitalized). Moreover, although constipation (which was more thoroughly discussed during the hearing than in the medical records or expert reports) was noted on a few medical records, none of the treaters attributed constipation to the beginning of her TM symptoms. Dr. Willer's arguments to the contrary are unpersuasive, while Dr. Lotze credibly explained how constipation would more likely reflect the existence of other neurologic issues, and thus have a somewhat (although not completely) secondary character.

Finally, I did not find compelling Petitioners' arguments attempting to pinpoint when W.M. displayed hypertonicity versus hypotonicity, and/or what stage she had reached in her disease process as of July 1. Again, the medical histories that the contemporaneous records contain are reliable, and they consistently point to an onset earlier than July 1. Dr. Willer's contention that a timeframe of onset on June 27 was incompatible with W.M.'s progression was unpersuasive—rather, the record is overall consistent with an onset a few days before Petitioners took W.M. to Affinity Clinic on July 1, 2013 (three days post-onset), with hospitalization by July 3. Dr. Lotze reasonably and credibly explained how this course would fit TM's progression to nadir.

Given my finding that onset likely occurred within a day of vaccination, I cannot find that Petitioners have successfully established that W.M.'s TM began in a medically acceptable timeframe, given their causation theory. Because TM is reasonably understood to be mediated by an autoimmune reaction involving antibodies or other immune cells associated with the *adaptive*, lagging immune response in reaction to antigenic exposure (here, from the Tdap vaccine), a relatively short onset timeframe is simply not medically acceptable. *See, e.g., Palattao*, 2019 WL 989380 at *34 (finding that a 30-36-hour period is too soon to be medically acceptable); *Mosley v. Sec'y of Health & Human Servs.*, No. 08-724V, 2015 WL 2354316, at *19 (Fed. Cl. Spec. Mstr. Apr. 27, 2015) ("onset of TM one day after tetanus vaccine is too soon to support vaccine

causation"); *Jagoe v. Sec'y of Health & Human Servs.*, No. 08-678V, 2012 WL 13036265, at *28 (Fed. Cl. Spec. Mstr. Aug. 3, 2012) (determining that TM symptoms occurring within 24 hours of vaccination were not a medically appropriate timeframe for vaccine causation); *Crosby v. Sec'y of Health & Human Servs.*, No. 08-799V, 2012 WL 13036266, at *38–39 (Fed. Cl. Spec. Mstr. June 20, 2012) (finding similar to *Jagoe* that 24 hours is too soon to infer vaccine causation for an injury of TM). In fact, an onset occurring within a day of vaccination points to an adaptive process that likely began *before* vaccination, since it would take several days from an inciting event (if that were the cause of TM—not something that can be reasonably assumed) for the antibodies that would drive TM to generate.

Dr. Willer did not successfully rebut the above. Rather, he unpersuasively cited to case reports involving pediatric cases of TM—but with onset timeframes consistently *longer* than what W.M. experienced. *See, e.g.*, Label at 426 (observing that onset began 11 days after rabies vaccination); Riel-Romero at 688–91 (mentioning that onset developed 17 days post-vaccination); Whittle at 1450 (noting that onset began 6-17 days post-vaccination). Dr. Gershwin mostly deferred to Dr. Willer's proposed onset and timeframe, and did not otherwise persuasively establish that an earlier timeframe was also medically acceptable, even if he proposed some scientifically plausible arguments for an innate-driven disease process. Dr. Moy, by contrast, accurately observed in providing his expert opinion that even if the mechanism at issue could be shown to be innate in nature (and hence cytokine-driven—contrary to Petitioners' causation theory), the process leading to clinical symptoms manifestation would still take more than 24 hours to "get up to speed" before symptoms would manifest. Moy Rep. at 7, 9.

Ultimately, Petitioners' arguments regarding the onset of W.M.'s TM symptoms are at odds with the evidence in this case, including their own consistent reporting to medical providers, as documented in the contemporaneous medical records. Their proposed timeline is not substantiated by the record. *See, e.g.*, Ex. 8 at 43–44, 54–55; Ex. 9 at 7; Ex. 10 at 24, 62, 149. Because a short timeframe for onset is not possible under Petitioner's causation theory, the onset that the record establishes cannot be deemed to have occurred in a medically acceptable timeframe after vaccination.

B. *Althen Prong One*

Although Petitioners assert that they have provided preponderant proof that meets each of the *Althen* prongs, they also maintain that a plausibility standard I applied in a different case is applicable to the first prong. *See* Post-Trial Br. at 59–62, 80, 105–06; *I.J. v. Sec'y of Health & Hum. Servs.*, No. 16-864V, 2022 WL 277555, at *5–6 (Fed. Cl. Spec. Mstr. Jan. 4, 2022). I utilized that lower standard in *I.J.* because that petitioner had successfully appealed my initial decision, and I was *obliged* on remand to follow the legal determinations made by the Court of Federal

Claims.[46] Remand did not, however, come from the Federal Circuit,[47] and thus *it does not control how I apply the legal standard herein.*

More significantly, there is good reason not to adopt a plausibility standard of proof to the first *Althen* prong in any case, since controlling Federal Circuit decisions *do not* stand for that supposition. *Boatmon*, 941 F.3d at 1359; *LaLonde,* 746 F.3d at 1339; *see also Moberly*, 592 F.3d at 1322. As the Circuit pointedly noted in *Moberly*, "proof of causation by . . . something closer to proof of a "plausible" or "possible" causal link between the vaccine and the injury . . . *is not the statutory standard*" (emphasis added). Nothing the Circuit has decided in the intervening ten to fifteen years suggests that this preponderant requirement has been abandoned. *Boatmon,* 941 F.3d at 1360 ("[w]e have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard").[48] Thus, I shall not apply a standard of mere plausibility in evaluating if Petitioners have successfully met the first prong's burden of proof.

Dr. Gershwin proposed a theory of molecular mimicry, arguing that the DTaP vaccine's antigens could mimic homologous sequences on the spinal cord resulting in cross-reactivity. But although he reliably described how this mechanism might apply to *other* autoimmune diseases or vaccines, he did not offer sufficient comparable evidence for the relevant context. As Dr. Moy noted, despite the prevalence of linear sequence homologies, autoimmunity does not occur in most cases—and if homology alone was enough, then autoimmunity would be much more common. Tr. at 468–69, 471. Thus (and as I have noted in many prior cases) the general reliability of molecular mimicry as a theoretic explanation for how *some* kinds of autoimmune conditions occur pathologically does not mean it applies in every single vaccine injury case. *See, e.g.*, *McKown v. Sec'y of Health & Hum. Servs.,* No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (citing *Devonshire v. Sec'y of Health & Hum. Servs.,* No. 99-031V, 2006 WL 2970418, at *15 (Fed. Cl. Spec. Mstr. Sept. 2006) ("[b]ut merely chanting the magic words 'molecular mimicry' in a Vaccine Act case does not render a causation theory scientifically reliable, absent *additional evidence* specifically tying the mechanism to the injury and/or vaccine in question") (emphasis in original), *mot. for review den'd,* 76 Fed. Cl. 452 (2007)).

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[46] In *I.J.*, I originally denied compensation after finding that the petitioner had offered insufficient preponderant evidence to establish that the Tdap vaccine can cause TM. *I.J.*, 2021 WL 1232733, at *30–34. However, the Court of Federal Claims granted review and subsequently vacated my prior determination, finding, among other things, that the plausibility standard should be applied. *I.J.*, 155 Fed. Cl. at 43. On remand, I applied the law to the claim as directed. *I.J.*, 2022 WL 277555, at *4 n. 5.

[47] Petitioners erroneously assert the contrary in their Post-Trial Brief. *See* Post-Trial Br. at 59 ("[t]he Federal Circuit stated in [*I.J.*] that it did not reject outright the "plausibility" standard for a medical theory").

[48] The Court in *I.J.,* by contrast, reasoned that a recent Circuit court decision had rejected *Boatmon* on the question of the standard applicable to the first prong. I explained in my remand decision that this was an unpersuasive and likely incorrect reading of the relevant decisions, although I applied the law as directed by the Court on remand. *I.J.*, 2022 WL 277555, at *4 n. 5.

Accordingly, the fact that this mechanism has been successfully invoked in other cases involving pediatric TM after receipt of *different* vaccines does not mean the same is true herein, no matter how reliable the theory is in a general sense.[49] *McGrail*, 2021 WL 1728706, at *25. Indeed, even cases involving TM and Tdap/DTaP referenced by Petitioners do not provide much in the way of persuasive guidance. Post-Trial Brief at 59; *see also Raymo v. Sec'y of Health & Hum. Servs.*, No. 11-654V, 2014 WL 1092274, at *21 (Fed. Cl. Spec. Mstr. Apr. 23, 2021). *Raymo* does not explain at all how components of the DTaP vaccine can cause TM, and was also decided before the advent of some relevant epidemiologic proof. *Compare* Post-Trial Br. at 59, citing *Raymo*, 2014 WL 1092274, at 20-21 ("[t]here are no epidemiologic studies of the causes of ATM, and thus no studies linking or refuting a link between the condition and vaccinations") *with* Baxter (published in 2016—two years after *Raymo*).

Otherwise, Dr. Gershwin marshalled limited reliable scientific or medical proof to make the kind of necessary connections between the DTaP vaccine and TM. He instead relied on case reports. But this kind of evidence as a general rule does not receive great weight when assessing causation. *See, e.g.*, *Campbell v. Sec'y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2011) ("[c]ase reports do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value ... [but] the fact that case reports can by their nature only present indicia of causation does not deprive them of all evidentiary weight."). And some of the items he offered have been specifically deemed unpersuasive before. Agmon-Levin, for example, has received criticism in the past for only identifying a small number of instances linking TM to vaccination—despite having reviewed *years* of published data in the search for such evidence. *See Pearson v. Sec'y of Health & Hum. Servs.*, No. 16-9V, 2019 WL 3852633, at *14 (Fed. Cl Spec. Mstr. July 31, 2019) (giving limited weight to Agmon-Levin in a case alleging that flu vaccine caused TM, since Agmon-Levin referenced only two post-flu vaccine TM cases—based on a review of *39 years* of published case reports) (emphasis in original). Others involved the COVID vaccine, which functions in a completely different manner,[50] and thus provided a poor comparison. Khan at 1–5; Khayat at 11.

[49] Indeed, Program findings specific to the Hepatitis B vaccine strengthen the conclusion that it can cause demyelinating conditions like TM. On October 13-14, 2004, former Special Master (and later Chief Judge of the Court of Federal Claims) Margaret Sweeney held a hearing—which became known as the "Hepatitis B – Neurological Demyelinating Omnibus Proceeding"—to determine whether a causal association exists between the Hepatitis B vaccine and several demyelinating illnesses (multiple sclerosis, TM, chronic inflammatory demyelinating polyneuropathy, and GBS) alleged in four paradigm cases. *Stevens*, 2006 WL 659525; *Werderitsh v. Sec'y of Dept. of Health & Hum. Servs.*, No. 99-638V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006); *Peugh v. Sec'y of Dept. of Health & Hum. Servs.,* No. 99-319V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8, 2007); *Gilbert v. Sec'y of Dept. of Health & Hum. Servs.,* No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006). These cases were then reassigned to former Special Master Laura Millman, who found that in all four cases, the Hepatitis B vaccine was causal. *Peugh*, 2007 WL 1006612, at *1, 17–18. No similar kind of determination has been made for DTaP or Tdap.

[50] The main type of COVID-19 vaccine in use relies on genetically engineered messenger RNA (mRNA), which gives cells instructions on how to make S protein found on the surface of the COVID-19 virus. *Different Types of COVID-*

There was also the epidemiologic evidence filed by Respondent. To be clear: this kind of proof is not dispositive of causation, and Petitioners are never affirmatively *required* to offer it. But (and contrary to Petitioners' arguments), it is relevant to the causation inquiry, nonetheless. *King v. Sec'y of Health & Hum. Servs.*, No. 03-584V, 2010 WL 892296, at *74 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) ("[c]onsistent with the teachings of *Daubert, Terran,* and *Grant,* special masters have routinely found that epidemiologic evidence, and/or other medical journal articles, while not *dispositive,* should be *considered* in evaluating scientific theories."). Indeed, as Dr. Moy observed, applicable epidemiologic studies have been employed as strong proof *in favor of* causation in other contexts. *See* Schonberger at 105 (connecting greater incidence of post-flu vaccine GBS). While the absence of such evidence cannot be held against a petitioner, it warrants evaluation *when it exists*.

Articles like Baxter suggested that there was no statistically significant association between TM and *any* vaccine. Baxter at 1456–61. It is reasonable to contend, as Petitioners do, that Baxter contains some methodologic weaknesses that limit how much probative weight its findings should receive. *I.J.*, 155 Fed. Cl. at 46–47. But it still undermines Petitioner's theory—especially given the degree to which Petitioners relied on case reports in the alternative. If *Baxter* only amounts to the aggregation of hundreds of thousands of individual case report instances in which the vaccine did *not* cause TM, to be disregarded as unpersuasive evidence rebutting causation, then why should the comparatively lesser sum of 37 instances (only 5 of which involved diphtheria and tetanus-containing vaccines) of post-vaccination causation noted in Agmon-Levin be given *more* weight?

This is not a case in which the Respondent's experts convincingly and completely rebutted Petitioners' causation arguments. To the contrary, many of Dr. Moy's contentions specific to causation were unpersuasive.[51] Dr. Gershwin for his part was a competent expert with demonstrated understanding of the topics relevant to the case, and his general assertions about autoimmune processes were reasonable. But ultimately it is the *claimant's burden* to prove causation.

In the end, I cannot conclude that the "can cause" prong was preponderantly met, although resolving this part of the claim proved more difficult than deciding the third prong. Certainly (and

19 Vaccines: How They Work, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/different-types-of-covid-19-vaccines/art-20506465 (last accessed Sept. 6, 2022). This is facially distinguishable from vaccines containing viral or bacterial particles, where the vaccine functions by provoking a direct adaptive response to its antigenic components.

[51] His arguments about the relevance of W.M.'s twin and her immune response did not appreciably undermine the possibility of vaccine causality, for example. And although I do not find that it was preponderantly shown in this case *how* weakening of the blood-brain barrier could have occurred in the relevant timeframe, sufficient for immune cells driving disease to reach the central nervous system, I also do not accept Dr. Moy's contentions about the singular importance of this factor under the circumstances.

given the number of cases finding a TM-vaccine association) causality remains an open issue in the Program, even if *in this case* Petitioners could not quite meet their burden. At bottom, Petitioners have clearly placed excessive weight on the temporal relationship between the date of vaccination and Petitioner's subsequent onset and diagnosis. Temporal association alone cannot establish causality—a concept well-understood in the Program. *Moberly*, 592 F.3d at 1323.

CONCLUSION

The Martinez family has my utmost sympathy for the suffering they have experienced, and I credit their demonstrated efforts to ameliorate W.M.'s condition and provide her with loving care. It is clear from this record that, based on the temporal coincidence of vaccination with evidence that she was ill, Petitioners reasonably believed the DTaP vaccine might have triggered her TM. But the record evidence does not support the claim.

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioners have not made such as showing. Petitioners are therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this decision.[52]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[52] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.